

Cardio Vascular Profiling System

VP-1000/2000

Non-invasive Vascular Screening Device

BP-203RPE II

Pulse Wave Unit

TU-100

Operation Manual



Important:

To operate this device properly and safely, please read this operation manual carefully before using it. Also, this manual should be located in a convenient place for future reference.

Caution

Principles

- No part of this manual should be reprinted or reproduce without permission from Omron Healthcare Co.
- Omron Healthcare Co. maintains right to modify the contents without prior notice.
- Ample care has been taken in writing this manual; please contact Omron Healthcare Co. if you have any questions about the content of this manual.
- If there are missing or disarranged pages, the manual will be exchanged. Inquire at the place of purchase.

Trade Mark

- Product names mentioned in this manual may be a trademark or a registered trademark of other companies.

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Before Use

Omron Healthcare Co. would like to thank you for purchasing this unit.

This device provides indices of PWV (pulse wave velocity), ABI (ankle-brachial index), pulse waveforms, mecanocardiogram and PCG to support early detection and diagnosis of arteriosclerosis.

The device you have purchased is comprised of the following components.

VP-2000	BP-203RPE II (Non-invasive Vascular Screening Device)
	TU-100 (Pulse Wave Unit)
	ST-200A (Trolley)
VP-1000	BP-203RPE II
	ST-100A (Trolley)

The VP-2000 includes a TU-100 (pulse wave unit) , check that the carotid arterial tonometric sensor and the femoral arterial tonometric sensor are included as components.

Please be sure to familiarize yourself with usage, warnings, capacity, and limitations in order to apply this device safely. After reading, please locate this manual in a convenient place for everyone who uses this device.

Important

In order to use this device correctly and safely, please read this manual carefully.
This manual should be located in a convenient place for future reference.

Indications for ensuring safety

In this manual and the device, there are indicating symbols that are designed to prevent hazards from body and properties and to promote correct and safe use. Those indications and meanings are explained as follows. Please familiarize yourself with these symbols before reading the manual.



DANGER indicates an eminently hazardous situation which, if not avoided, will result in death or serious injury.



WARNING indicates a potentially hazardous situation that, if not avoided, may result in death or serious injury.



CAUTION indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.



△ Indicates the existence of contents which are included within or nearby the symbol. (In this case the symbol warns us of the possibility of electrical shock.)



⊘ Indicates a prohibited behavior. Specific instructions are included within or nearby the symbol. (In this case, prohibiting disassembly.)



● Indicates necessary action or instructional information. Specific instructions are included within or nearby the symbol. (In this case, pulling the power cord by its connector.)

Other symbols

CAUTION!

It indicates information that should be known when operating this device.



DANGER



Do not use this device in the presence of a flammable anesthetic mixture with ignitable gas or oxygen or nitrous oxide. It will cause an explosion.



WARNING



Only doctors or authorized personnel should attempt to operate this unit. Please do not allow patients to operate this unit in order to avoid accident.



This unit is designed to conduct examinations.

This unit is not intended for monitoring patients in the ICU, OR and ER.



This unit cannot be used in the following places:

Rooms that cause electrical noise such as MRI room, CT, X-ray room, operational room with the electrosurgical unit, rooms with microwaves, etc.

Also, avoid using other medical equipment while using this unit.



During the examinations, operator should sit with the unit and by the patient, and pay attention to the status constantly.



This unit can be damaged by the electric energy from a defibrillator. During defibrillation, remove the sensors from a patient.



Do not operate a cellular and/or radio trans-receiver in the presence of this unit in order to avoid malfunction.



Use only authorized accessories and options in order to avoid accident.



Please be familiar with manuals accompanied with accessories and options. There is no warning about accessories and options.



Do not disassemble or reconstruct medical electron instrument in order to avoid fire and electrification.



Operate the equipment at the voltage described on the rating label to avoid fire and electrocution.



In case of using this device for patients with infection, device itself, cuffs and sensors are necessary to be cleaned and sterilized before using for other patients.



To operate this unit safely and properly, please inspect this unit before use.



WARNING



Do not put anything on top of this unit in order to avoid fire and electrocution.



Do not place heavy materials on the AC power cord in order to avoid fire and electrocution.



During maintenance, turn OFF and unplug the AC cord in order to avoid electrocution.



**If the following failures occur, turn OFF and unplug the AC cord.
Ignoring the following conditions may cause fire and electrocution.**

- Smoke, or the detection of smoke by smell.
- Dropping device.
- Liquid leaks into the unit.
- Equipment malfunction.



If the failure occurs as mentioned above, please promptly follow directions below.

1. Confirm the AC plug is unplugged.
2. Place a sign "Do not use, out of order" on the front of monitor.



Do not expose this device to direct, strong sunlight or leave it in a sun-heated car as this may lead to problems.



During operation, check regularly if the unit is working properly.



This unit and the accessories are precision instruments. In case of high impact, only use it after confirming problem-free operation.



Do not tilt more than 10-degrees. It may topple over and cause injury.



Heart Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias.
Do not rely entirely upon rate meter alarm.
Keep pacemaker patient under close surveillance.
See this manual for disclosure of the pacemaker pulse rejection capability of instrument.



Do not connect any electric device that does not meet the standard of IEC60601-1, or not fulfilling IEC60601-1-1.

Neglecting this caution could cause electric shock to the device.

For the use of a PC or a printer with this device, the connecting device should be approved according to standards mentioned above.

(This unit meets the restricted level of leakage current required for medical devices and it does not include all the connected devices. Connecting to other device is not allowed unless the total leakage current of such a combination is within the restricted level.)

WARNINGS and CAUTIONS for Safe Measurement



Patient must meet following conditions.

- Height 120 - 210 cm
- Circumference of arm 16 - 38 cm
- Circumference of ankle 17 - 33 cm

Measurements may not be valid for a patient who is using a pace maker.

WARNINGS and CAUTIONS for blood pressure measurement



- When it is impossible to complete a test or there are doubts about the measurement values, please confirm the patient's condition. The patient's condition may have deteriorated to the point where measurement limits are exceeded. Always verify that the cuff and cuff hoses are appropriately used and are not bent or blocked.

If the display shows 0, the monitor's pressure may be 0. But if the cuff hose is blocked or bent there may be air remaining in the cuff. At this time disconnect the hose from the cuff to ensure that blood flow is not restricted, re-attach and try again.

- Blood pressure measurement is conducted by putting pressure on arms and ankles and a patient may feel pain or have temporary macula caused by internal bleeding. Although this macula will disappear, inform concerned patients about the possibility in advance. In some cases, the inflation value needs to be adjusted.
- Stop the measurement if the patient expresses pain.



In the following cases, do not wrap the cuff on the relevant parts;

- Arm with intravenous drip
- Arm with hemodialysis shunt
- Lower extremity with deep-vein thrombosis



Measurements are not possible in the following cases:

- Patients with insufficient peripheral circulation, acute cases of low blood pressure, low temperature.
- Patients with a high frequency of arrhythmias.



In the following cases, follow the physician's instructions.

- If there is acute inflammation, purulent disease, external wound etc., on the part of the body where the cuff is applied.



In case a patient is confined to bed for a long time, take measurement after checking for thrombus.

WARNINGS and CAUTIONS for Safe Measurement



In the following cases, proper measurements may not be possible:

- If the motion artifact occurs by convulsion with a patient due to rheumatism etc.,
- If the patient has diabetic arteriosclerosis.
- If the patient has quasi-hypertension.
- When the cuff position is above or below the heart level.
- When the patient moves or talks during a measurement.
- When the cuff is placed over thick clothing.
- When a tucked up sleeve is adding pressure on the arm.
- If the patient has cardiac murmur
- If the patient has abnormal 2nd sound.
- If the patient has noise during respiration
- If the patient has convulsions or shivering

WARNINGS and CAUTIONS during ECG monitoring



In the following cases, proper measurements cannot be taken:

- Patients with a high frequency of arrhythmias.
- Patients who use a pace maker.



Following clothes are suitable for examination:

- Thin sleeves
Cuffs are wrapped on the brachial so a patient can wear thin sleeves or leave the arm uncovered. Do not roll up the sleeves, even thin ones, as it may cause the measurement to fail.
- Take off socks and thick tights.
Cuffs are wrapped on the ankle so have the patient remove their socks or thick tights.

WARNINGS and CAUTIONS during Pulse wave detection



Follow directions below when placing CAP sensor on a patient.

- Do not use for a patient whom carotid sinus hypersensitivity is suspected.
- Do not leave CAP sensor on a patient for more than 10 minutes.
- Stay with a patient during measurement. Always check a patient's condition.
- Remove CAP sensor immediately when a patient feels pain or discomfort.

CAUTIONS of Use



The unit should be installed in the following locations and provide:

- Power supply should be within $120V \pm 10\%$.
 - A level and stable surface for the unit to sit on.
 - A location with the appropriate space required for airflow.
 - Ambient temperature between 10 - 40°C and humidity less than 85%.
-



This device is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings use for domestic purposes.



The following locations are not suitable for installing the unit:

- A location where direct sunlight is on the unit for an extended period of time. (Deterioration of the liquid crystal display will occur.)
 - A location where the unit may be splashed with liquids.
 - A location where extreme shock and vibrations may damage the unit.
 - A location where gas and fire may be present.
-



The following locations are not suitable for storing the unit:

- Ambient temperatures decrease below -20°C or higher than 60°C or the humidity exceeds 95%.
 - A location where chemical products are stored.
 - Environment with extremes of temperature.
If this unit is left exposed to direct, strong sunlight, or in a sun-heated car, the LCD becomes an isotopic liquid. This process cannot be reversed and the display is rendered unusable. Alternatively, the case may become deformed, leading to other problems.
-



If condensation is present on the unit, disconnect the monitor from AC power, and dry the unit with a dry cloth. Condensation could lead to electric shock and other mechanical problems with the monitor.



While the monitor is in use, constant monitoring of the unit will ensure user as well as patient safety.



In case of condensation inside the device, remove AC cord from the device and dry inside enough before use.



Always grasp the plug or connector when disconnecting any of the cords. Pulling on the cord could cause damage.

CAUTIONS of Use



Cautions are required for AC power plug in order to avoid electric shock and fire.

- Do not touch AC power plug with wet hands.
 - Do not pull AC power cord while unplugging AC power plug.
 - Unplug AC power plug from outlet when this device is not operated for long periods of time.
-



When cleaning the unit avoid using any solvents like thinner or benzene. Cleaning with these agents may cause damage to the monitor's exterior.



- In case the unit is brought in from hot weather or a sun-heated car, leave it to cool for at least one hour at room temperature (10 to 40°C) before using it.
The unit may break down or correct measurements cannot be taken.
-



- When the unit is brought in from the cold to a warm room, water droplets may collect inside the machine. In this case, allow them to evaporate fully and then power it on.
Otherwise, it may cause electric shock or unit failure.
-



- Store the sensor gel below room temperature 10 to 35°C, avoiding high temperature and humidity, and direct light.
If the sensor gel gets dry, correct measurements cannot be performed.
-



- In an environment with micro vibrations, these micro vibrations may affect the PCG sensor and cuff, and measurement may not be possible. In this case, take measurement after stopping the vibrations.
-



Follow directions below in order to prevent CF card data from being damaged.

- 1) Do not turn off the switch while recording data into CF card.
 - 2) Turn off the switch while inserting CF card in and removing from a device.
 - 3) Do not disassemble CF card nor remodel it.
 - 4) Do not expose CF card to static electricity when handling it out of the device.
 - 5) Do not bend CF card nor put heavy materials on it.
 - 6) Do not get CF card wet. keep it dry.
 - 7) Be sure not to turn off the power during printing. CF memory may be damaged.
 - 8) Use Colin's original CF card; generic CF cards cannot be used in the unit.
-

Outline

This unit is designed to measure ABI (Ankle-Brachial Index) and PWV (Pulse Wave Velocity), which are to be used for evaluation of Arteriosclerosis. STI (Systolic Time Interval), which is useful for evaluation of cardiac functions, can be measured with Pulse Wave Unit TU-100(VP-2000). The measurement results are displayed on a colored LCD, and are recorded by the external printer.

Special features

- Easy operation
By using attachable Brachial and ankle cuffs, the Doppler blood flow sensor, that requires skilled application, is not needed.
- High accuracy and high reliability
Specially developed tonometer, carotid artery sensor, phonocardiography, and signal transaction are accurate and reproducible.
- ABI measurement by measuring 4 limbs simultaneously
In ABI, systolic blood pressure of 4 limbs is simultaneously measured.
- Non-invasive measurement of ABI and PWV
Arteriosclerosis is totally evaluated by ABI and PWV. It is effective to evaluate arterioacleriosis of the patient with Pseudo-hypertension caused by diabetic arteriosclerosis.
- Color LCD
The color LCD display makes viewing the measured data easy.

Explanation of Technical Terms

PWV (Pulse Wave Velocity)

Pulse wave velocity is the speed at which the pulse is transmitted from the heart to the end artery when blood is expelled during contraction. It is mainly used to evaluate hardness of the artery wall.

$$PWV = \frac{L \text{ (distance)} \times 1}{PTT \text{ (Pulse Transit Time)}}$$

With this device, the PTT of each segment is calculated from the waveform taken from each sensor as shown in the illustration below.

Ascending Aorta - Carotid Artery

$$hcPWV \times 2 = \frac{L_{hc}}{T_c}$$

Ascending Aorta - Right Brachial

$$hbPWV = \frac{L_{hb}}{T_b}$$

Ascending Aorta - Femoral Artery

$$hfPWV \times 2 = \frac{L_{hf}}{T_c + T_{cf}}$$

Femoral Artery - Ankle PWV

$$faPWV \times 2 = \frac{L_{fa}}{T_{fa}}$$

Right Brachial - Ankle

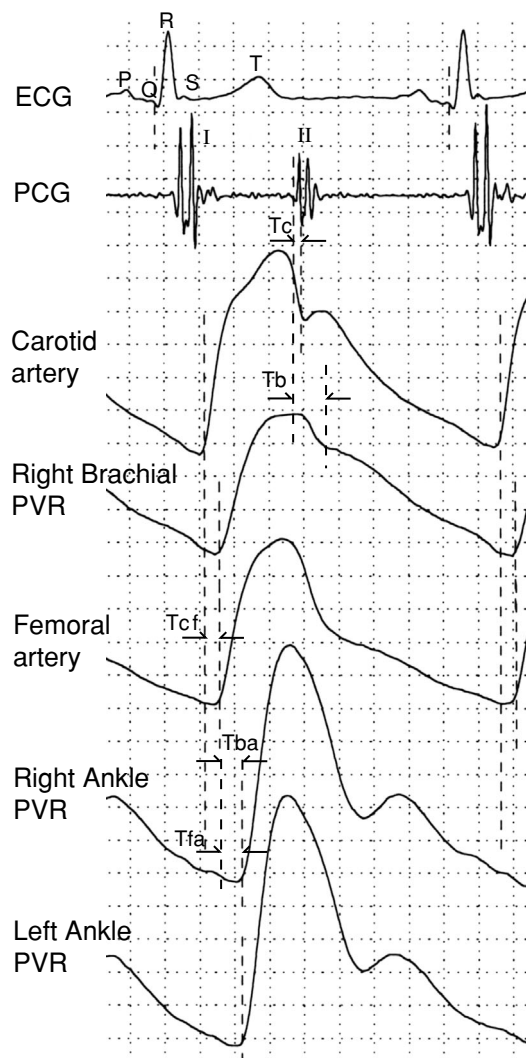
$$baPWV = \frac{L_{ba}}{T_{ba}}$$

Ascending Aorta -Ankle PWV

$$haPWV = \frac{L_{ha}}{T_b + T_{ba}}$$

※1: Distance to be measured is automatically calculated by patient's height based on statistical studies.

※2: Pulse Wave Unit TU-100 is a optional unit for VP-1000



HR (Heart Rate)

HR stands for heart rate in a patient during measurement. It is calculated by a moving average for 4 or 8 beats of R-wave interval of ECG signal and is indicated by a numerical value converted to heartbeats for 1 minute. Numerical unit is bpm(beat per minutes)

STI (Systolic Time Interval)

ET, PEP, etc., are generally called STI, used for quantitative evaluation of cardiac functions.

ET (Ejection Time)

The time from the opening of the aortic valve to the closing. The regular value is 285 ± 25 msec, but may decrease with an increase in heart action. Also, it will increase with an increase in the heart contraction volume, and decrease with a decrease in the heart contraction volume.

PEP (Pre-Ejection Period)

The time between electrical agitation in the heart chamber and the opening of the aortic valve. The regular value is 96 ± 10 msec. It will increase with a decrease in the heart action, or decrease with an acceleration of heart action.

ET/PEP (Ejection Index)

The average value for a regular example is 2.94 ± 0.54

Regular reaction: $2.5 < \text{ET/PEP} < 3.6$ (PEP < 106 msec)

Volume reaction: $\text{ET/PEP} \geq 3.6$ (PEP < 106 msec) Heart action acceleration illness condition

Pressure reaction: $\text{ET/PEP} \geq 2.5$ (PEP ≥ 106 msec) Heart action reduction illness condition
ET/PEP shows the relation between Left Ventricular End Diastolic Volume (LVEDP, LVEDP), Ejection Fraction (EF), Stroke Volume (SV), and Ventricular Contraction Fraction (VCF).

Q-II Overall control period

The time from the start of the ECG Q wave to the closing of the aortic valve (11 beats)

ABI (Ankle Brachial Index)

ABI is found as shown below.

$$\text{ABI} = \frac{\text{Ankle systolic pressure}}{\text{Brachial systolic pressure}}$$

By using the ABI, Arteriosclerosis Obliterans can be diagnosed, and the overall health condition of all heart blood vessels can be evaluated. ABI is mainly used to evaluate Atherosclerosis (finding the inner radius of the blood vessel and blockage condition by atheroma (lipid)).

PCG (Phonocardiogram)

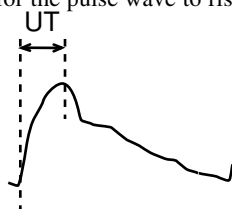
Phonocardiogram detects heart sound.

PVR (Pulse Volume Record)

Volume pulse wave record. Ankle PVR is taken by the sensor in the dual chamber ankle cuff.

UT (Upstroke Time)

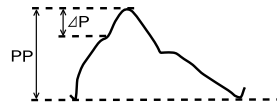
Time for the pulse wave to rise.



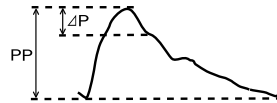
AI (Argumentation Index)

Augmentation index is a numerical value that displays the percentage of the reflected pressure wave with respect to the effected pressure wave in the brachial pressure pulse wave. ΔP expresses the post-systolic component after subtraction of the maximum wave height of the pre-systolic component.

$$AI = \frac{\Delta P}{PP} \times 100 (\%)$$



Example of the increase in the AI value as the wave height of the post-systolic component rises

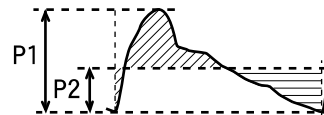


Example of the decrease in the AI value as the wave height of the pre-systolic component rises



%MAP

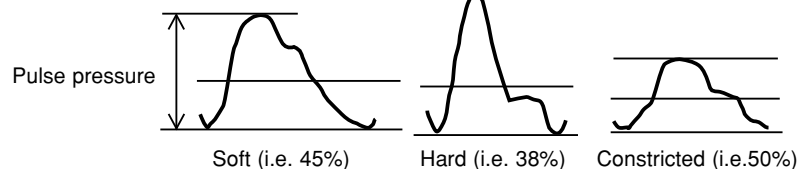
This value is one of the pulse waveform indexes that is calculated from the blood pressure values. It expresses, as a percentage, a value from the area of the wave form (P2) divided by the amplitude of the pulse (P1). This value is calculated with the following formula:

$$\%MAP = \frac{P2}{P1} \times 100 (\%)$$



P1 : Pulse wave amplitude

P2 : Mean value of the area
(the level at which  and  are equal.)



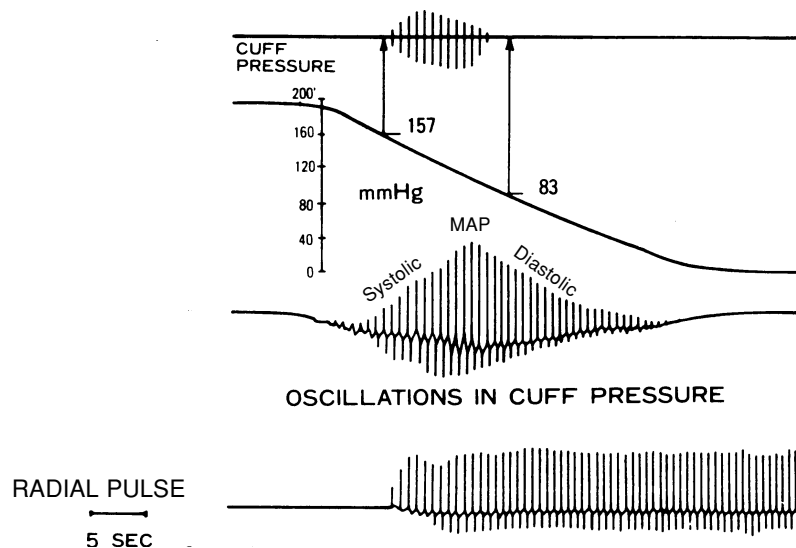
Measurement Principle of NIBP

Oscillometric Method

This method measures the blood pressure by detecting the pulsation of the artery which is caused by the contraction of the heart, as the pressure oscillation in the cuff. When the cuff around the upper arm is fully inflated, blood flow stops but pulsation of the artery continues and causes oscillation of the pressure in the cuff. As the pressure in the cuff is decreased slowly, the magnitude of the pressure oscillation in the cuff gradually increases and eventually reaches a peak. Further decrease of the cuff pressure causes the oscillation to decrease. The relationship between the changes of cuff pressure and its oscillation is stored in memory and used to determine blood pressure. Namely, cuff pressure when the oscillation increases rapidly is taken as the systolic pressure, and that when the oscillation decreases rapidly is taken as the diastolic pressure. Cuff pressure when the oscillation reaches a peak is taken as the mean arterial pressure (MAP).

The oscillometric method does not determine blood pressure instantaneously unlike the auscultatory method and microphone type automatic blood pressure monitor, but determines it from the curves of the changes of the pressure and its oscillation as described above. This feature gives it antinoise characteristics as it is not affected by external noise or electric surgical units.

KOROTKOV SOUNDS

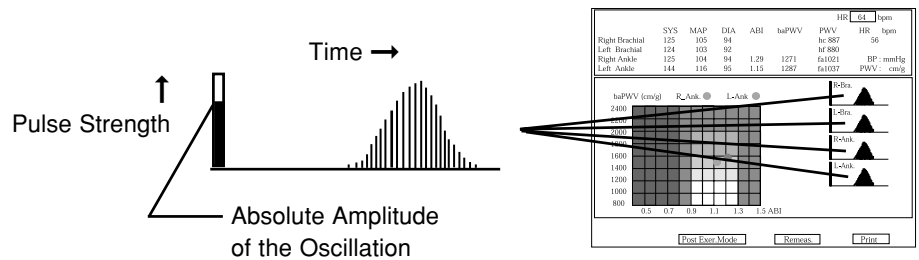


Comparison among the auscultatory, oscillometric and palpatory methods of measuring blood pressures.

SOURCE: MEASUREMENT OF BLOOD PRESSURE BY
L.A.GEDDES

Display of the Oscillation Graph (Change Patterns of Pulses)

The unit displays an NIBP oscillation graph after each measurement.

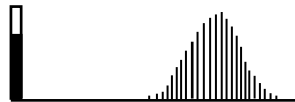


Validation with the Graphic Waveform (Change Patterns of Pulses)

The reliability of measurement results can be checked based on the display of the graphic waveforms. If there are any doubts about measurement results, check the graphic waveforms.

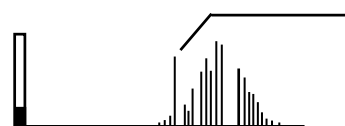
Good Measurement

The display below is a mountain shape and reliability of the measurement is high without noise such as motion artifact.



Low Reliability of Measurement

The display below is not mountain shaped. Noise (motion artifact) has interfered with the measurement.



Signal that can be considered as noise.
From the graphic waveform, it can be considered that the blood pressure reading was faulty.

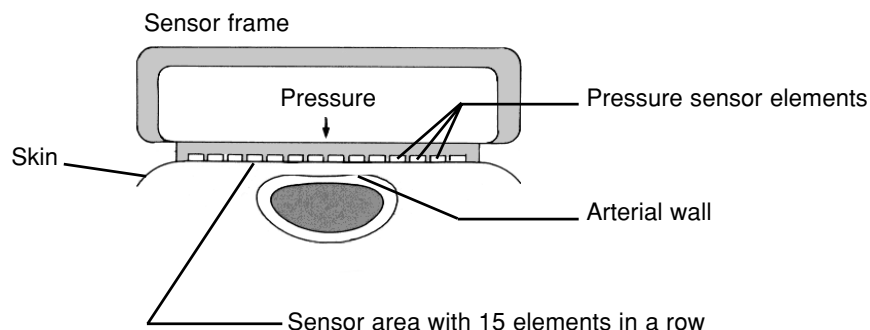
Outline of TU-100 (only for VP-2000)

About the product

The TU-100 is a device that uses the tonometry method to measure pulse waveforms. Connect it to the BP-203RPEII for operation.

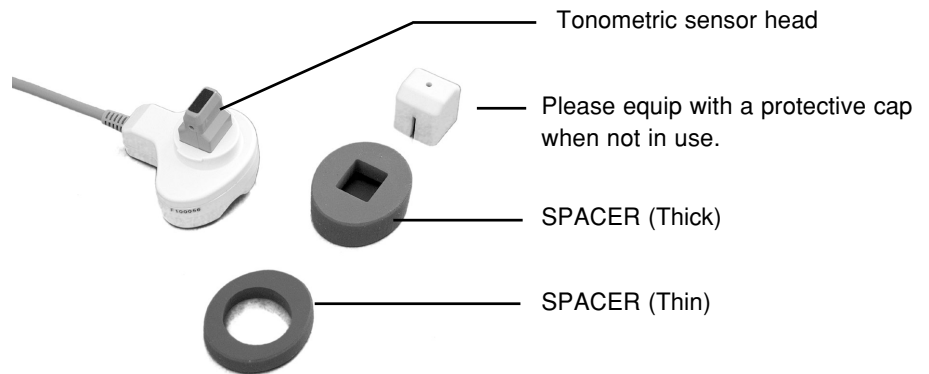
Pulse wave detection

The TU-100 and tonometric sensors employ the tonometry method for pulse wave detection. By the tonometric method, the pressure pulse wave sensor pushes on the artery so an area of the artery is flattened. When the wall of the blood vessel is flat, the inner pressure of the artery is communicated directly to the pressure sensor. The pressure sensor contains a row of 15 elements. The main unit of the BP-203RPEII analyzes the signal from the pressure sensor, and from the 15 elements selects those in the most suitable position. The pulse pressure measurements from those elements are used in analysis.



CAP/FAP SENSOR (Carotid Arterial Pulse, Femoral Arterial Pulse)

The SENSOR is primarily used on the tonometric sensor head for measurement of large arterial pulse waves, but it can be applied to other areas.



The SENSOR can be pressed down using the appropriate pressure, if an attached spacer is inserted.



Use of a spacer stabilizes inclination.

The thicker SPACER is used for subjects with average weight.



The thinner SPACER is used for subjects with above average weight.



If the BELT LOOP is attached to the FAP SENSOR, it can be fixed to a strap.

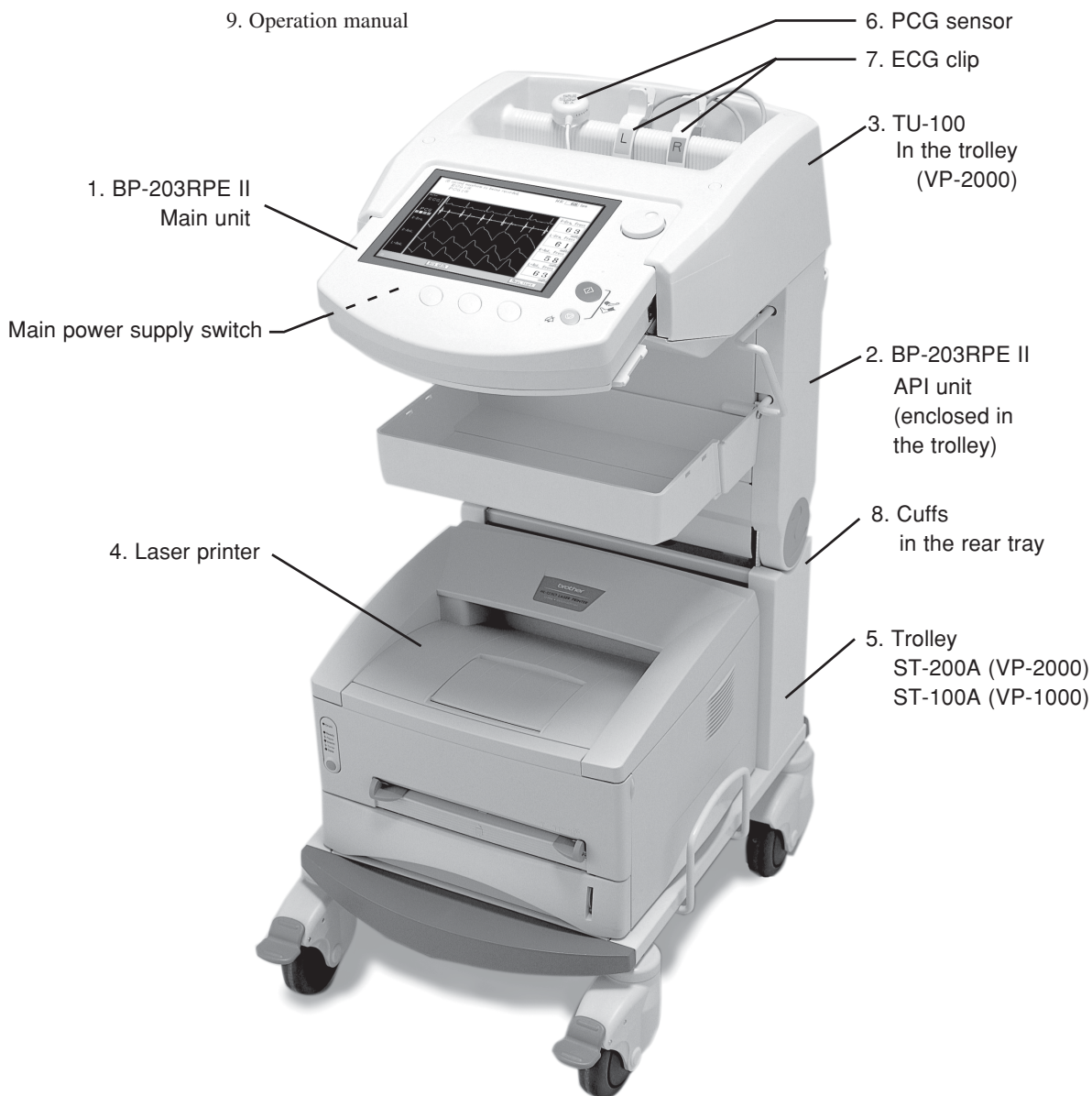


The SENSOR head is made to be very precise and delicate. Applying undue strength or treating it roughly may cause damage. Please equip with a protective cap after using FAP SENSOR, and store it in a secure location.

Configuration

This device includes the following components. Verify before using.

1. BP-203RPE II Main unit
2. BP-203RPE II API unit
3. TU-100 (only for VP-2000)
4. Laser printer
5. Trolley ST-100A(VP-1000), ST-200A(VP-2000)
6. PCG sensor
7. ECG clip
8. Cuffs in the rear tray, 1 set regular size, 1 set large size (Ankle+Brachial)
9. Operation manual



The appearance of the system is subject to change without the prior notice.



■ Use only authorized accessories and options in order to avoid problems.

Standard Accessories

ECG ELECTRODES CLIP



PCG SENSOR



13cm STANDARD BRACHIAL CUFFS
15cm LARGE BRACHIAL CUFFS



CUFF HOSE × 2



13cm STANDARD ANKLE CUFFS
15cm LARGE ANKLE CUFFS



SENSOR CABLE UNIT
(ANKLE CUFF HOSE)



PCG SENSOR WEIGHT



Optional Accessories

SENSOR GEL PACK 101S
20 packs



GROUNDING WIRE



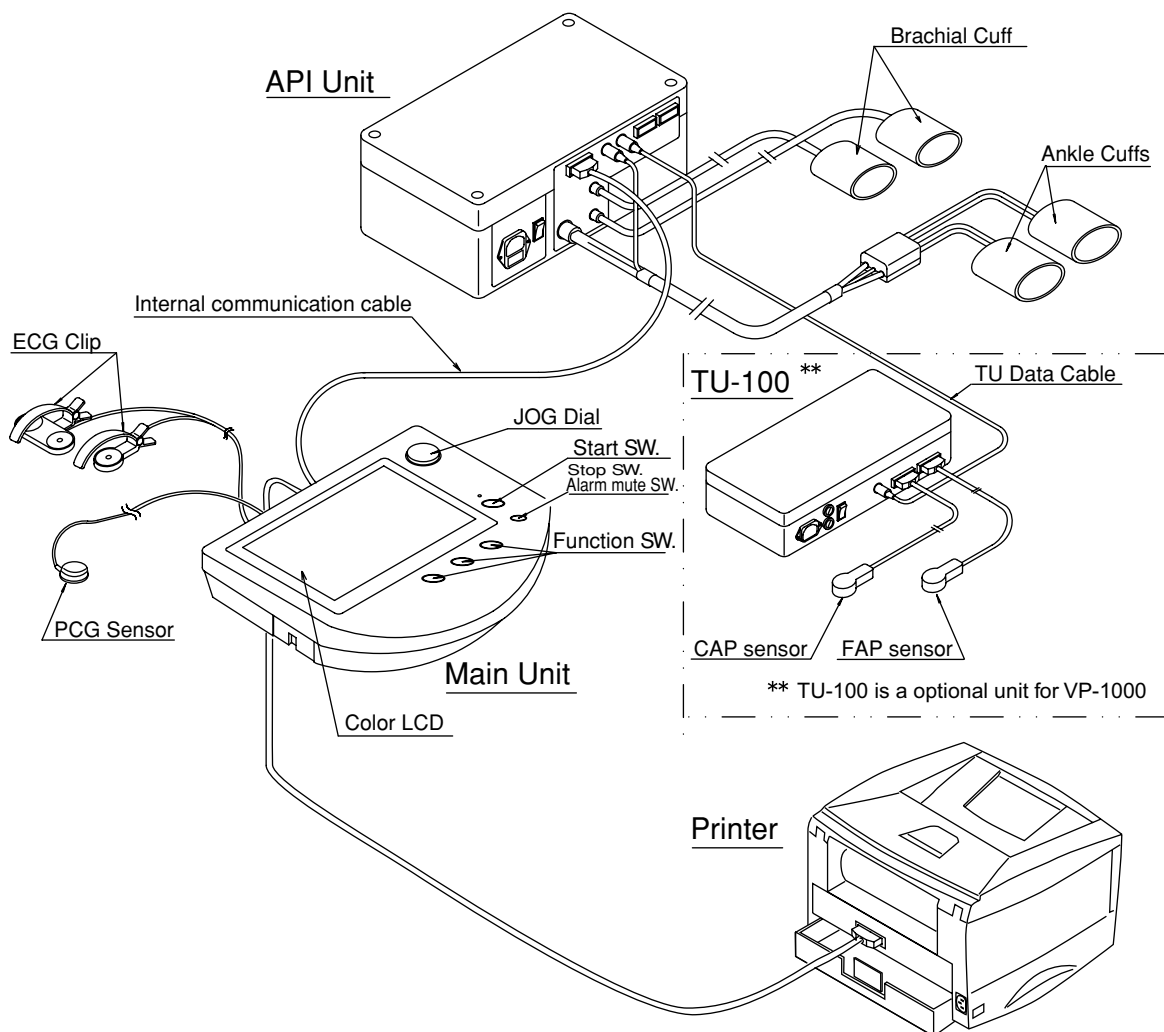
VELCRO SET



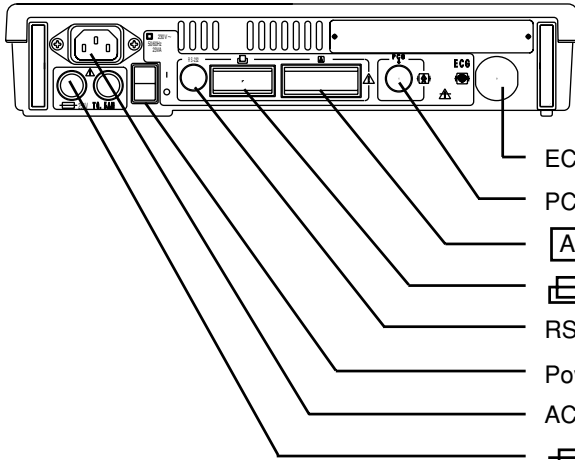
Identification

Whole unit

Name of each part and concise functions are described.




Main unit rear view



ECG : Connector for the ECG cable.

PCG : Connector for the PCG sensor.


A : Connector to the API unit.

 : Connector for the printer cable.

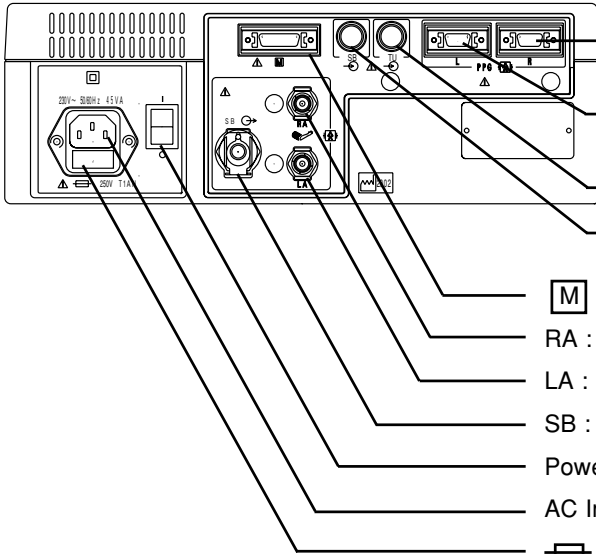
RS-232 : Serial communication port

Power switch : Always leave it On.*

AC Inlet : Connector for AC power cord.

 : Fuse. Please contact our customer service center when fuses are blown.

API unit rear view



PPG (R) : Connector for the PPG (R) sensor.
(as an option)

PPG (L) : Connector for the PPG (L) sensor.
(as an option)

TU : Connector to the TU-100.

SB : Connector for the L/R ankle cuff signal cable.

M : Connector to the main unit.


RA : Connector for the right brachial cuff hose.

LA : Connector for the left brachial cuff hose.

SB : Connector for the L/R ankle cuff hose.

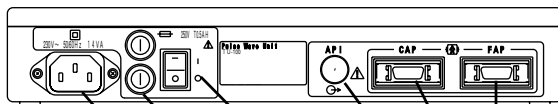
Power switch: Leave it ON.*

AC Inlet: Connector for AC power cord.

 : Fuse. Please contact our customer service center when fuses are blown.

* Power switch: To turn power on or off, use the main power switch on the trolley. Refer to page 19 for its location.

TU-100 rear view



FAP : Connector for the FAP sensor.


CAP : Connector for the CAP sensor.

API : Connector for the API unit.

Power switch: Leave it ON.

(To turn power on or off, use the main power switch on the stand.

Refer to page 28 for its location.)

 : Fuse. Please contact your local distributor when fuses are blown.

AC Inlet : Connect the power cord.



Please be sure to turn off the main power switch, before removing or connecting each unit and sensors. Not doing so may cause electric shock or device failure.

Meaning of the Symbols

Meaning of the symbols on the front panel



Measurement START switch



Measurement STOP switch



Alarm mute

Meaning of the symbols on the rear and side panel



Refer to manual



Type BF: Classification by leakage current levels with defibrillation protection.



Type CF: Classification by leakage current levels with defibrillation protected.



Class II Equipment



Compact Flash memory card



BRACHIAL CUFF



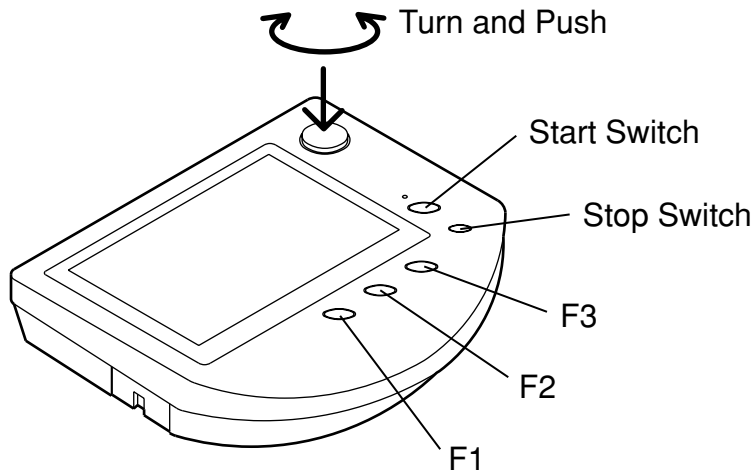
INPUT



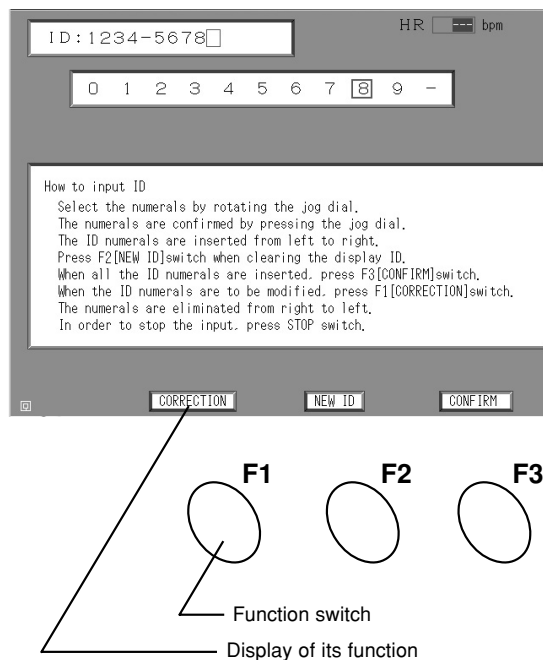
OUTPUT

Jog Dial and Function Switch

Jog dial can be turned and pushed, to select and edit.



The function switch's operation is as labeled on LCD screen.



Initial Screen

The initial screen is displayed soon after power is switched on.

The initial screen displays the following information:

- Top right: HR bpm
- Top left box: In case of ABI measurement input ID or patient personal information and place the brachial cuff and the ankle cuff.
- Top right box: R-Bra, Prs mmHg, L-Bra, Prs mmHg, R-Ank, Prs mmHg, L-Ank, Prs mmHg
- Bottom left box: Confirm the following items at the installation.
Verify that ECG/POG electrodes are not dry.
Wrap the brachial cuff so that the air hose tube is located on the outside of arm and faced towards the patient's head.
Wrap the ankle cuff on a bare ankle so that the cuff hose tube locates at the posterior tibiales artery.
Relax the patient and start the measurement.
- Bottom: Menu button and Meas. button.

Below the screen, the buttons are labeled: Menu (F1) and Meas. (F3).

- To perform a test, press [Meas. (F3)].
For test procedures and results, see “Measurement Procedure” (page 31).
- To make basic device settings or to process past test data, press [Menu (F1)].
For details, see “Settings” (page 77).

Installation



WARNING



Potential hazard

Do not use this system in the presence of a flammable anesthetic or in a hyperbaric chamber or oxygen tent.

Method of installation

The BP-203RPE II and TU-100 are designed to mount to the supplied trolley ST-200A. The authorized service personnel of Omron Healthcare Co. or an authorized distributor will assemble and install this system.

The device shall be setup by the bed side .
Air hoses and cable assemblies shall be put in undisturbed place or shall be fixed to a bed with velcro strips

Caster wheel
Please lock the casters when the device is in use and unlock when moving the system.



CAUTION

Caution to the place of installation

The following locations are not suitable for installing the unit:

- A location where the system may be splashed with any liquid or potential contact with steam.
- A location where direct sunlight is on the unit.

Cautions for installation

- Do not put heavy materials on this unit.
It may become out of balance and fall. Falling object may become the cause of an injury.

Caution during transfer

- Turn off, unplug the AC, and remove the sensors from the patient before transfer.
- Unlock the stand before transfer.
- Please take a special care for the stand not to fall due to unstable balance when you move the stand without printer loaded.

Power On Procedure

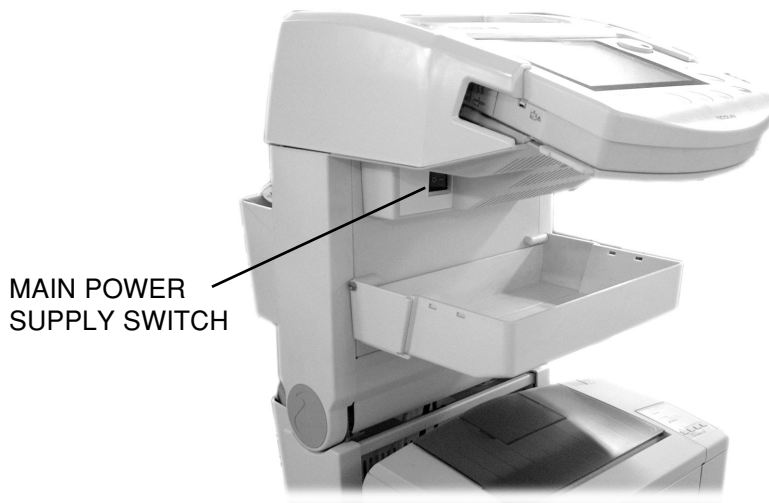
Cautions for Tonometric Sensor (CAP / FAP sensor) for VP-2000



- Be sure to turn off the Power when Tonometric Sensor is plugged in / pulled out of TU-100, or the internal circuit of Sensor may break down. Accidentally plugged in / pulled out with power on, turn Power off and on again for a correct measurement.

With the trolley

To turn on the power, use the Main power supply switch on the left side of the trolley.



In case of “No Power”, please verify that unit power switches are “ON” for the TU-100, API Unit and MAIN Unit in order.

When Power of API Unit or TU-100 is turned off during operation, "Communication Error", as System error, will be displayed on the screen. In this case, power cycle each Unit again, in accordance with the procedure above.

Check before Use



For safe and proper use, the machine has to be checked before use.

Prior to daily use, the following points should be checked:

Before turning the power ON

Appearance

- No deformation due to falling?
- Is the unit clean?
- Is the unit wet?

Power Cord

- Is the power cord secure at the main unit connector?
- No heavy object placed on the power cord?
- No damage to the power cord? (No core showing? Cut?)
- Is the power cord connected to an outlet with a grounding wire?

Printer

- Is the printer paper enough?

After turning the power ON

Appearance

- No smoke or abnormal smell?
- No abnormal noise?

Time Indication

- Is the clock correct?

NIBP

- Is the proper sized cuff for the patient's arm and ankle prepared?
- Are the connections of the cuff hose and cuff secure?

ECG and PCG

- Are the ECG electrodes and PCG sensor gels new?

Turn ON/OFF the device

Use the main power switch located on the stand to turn ON/OFF the device.

When turning ON the device;

- Do not attach the ECG clips to the patient;
- Do not touch or move the ECG clips.

System information

In contacting our customer service and referring to manuals, please note the system version. The system version can be checked in the procedure below.

In accordance with Menu Screen,

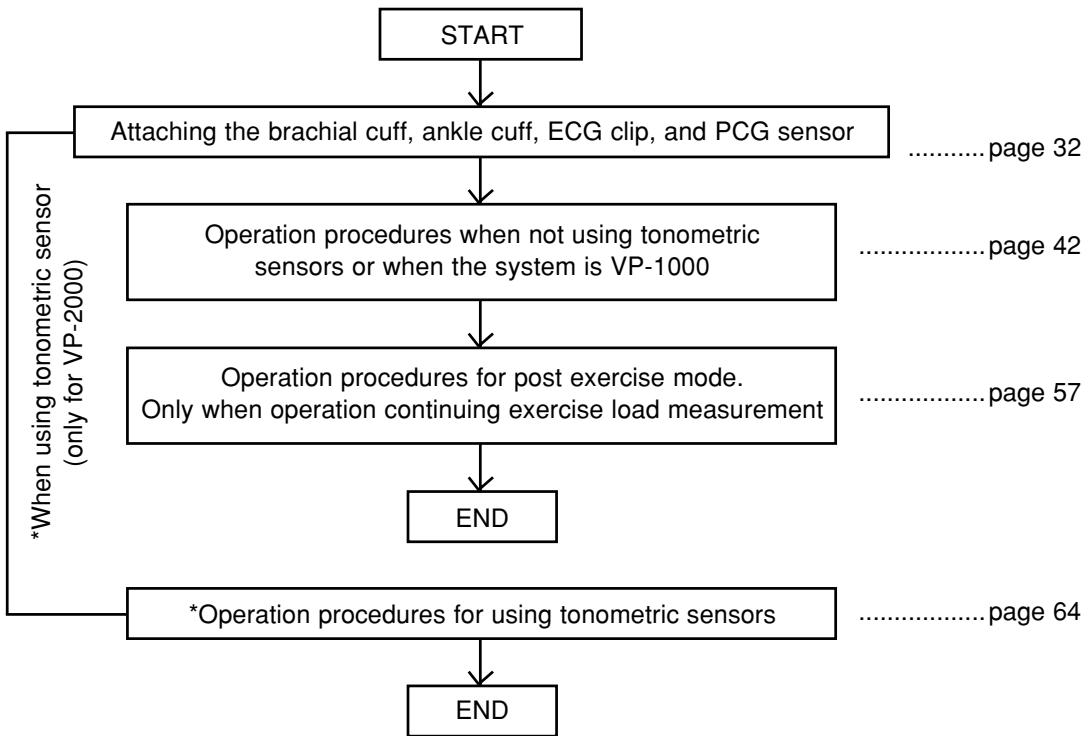
- Select Menu
- select "5.System Information"
- press jog dial.
- System version number is indicated on the display

Memo

Measurement Procedure

Measurement procedure is different when tonometric sensor is used. Please follow the flow chart below.

Flow of this chapter (Contents)



WARNING

To avoid any accident, read **WARNING** and **CAUTIONS** indicated in "Check Before Use" carefully, before the operation.

Application of the BRACHIAL CUFF

Cuff Selection

The STANDARD BRACHIAL CUFF included with the VP-1000/2000 can be used to take the measurement of a patient whose arm circumference is 23 cm to 38 cm.

Choosing an appropriate cuff for the patient is necessary to obtain an accurate measurement. Choose a cuff appropriate for the patient by referring to the table below. To attach to the cuff hose, insert the hose and turn it clockwise to lock.

Name	Arm circumference (cm)	Bladder width (cm)
CUFF No. 20, 21 Standard accessory	23 to 33	13
CUFF No. 7, 8 Standard accessory	17 to 26	10
CUFF No. 5, 6 Optional accessory	32 to 38	15



Choose the appropriate cuff to avoid any error caused by gap between cuff and arm in the measurements.

If the cuff used is too large, the blood pressure measurement may be lower than the actual value. If the cuff used is too small, the blood pressure measurement may be higher than the actual value.

Check that there is no looseness in the connection area. If there is an air leakage, correct measurements can not be taken.

Apply the BRACHIAL CUFF to the upper arm of the patient. The BRACHIAL CUFF are different for the right and left arms. Do not apply the wrong one.



■ If the patient has an internal shunt for dialysis, do not apply the cuff to the arm with the shunt. Measure only at the arm that does not have an internal shunt.

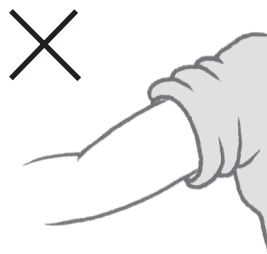
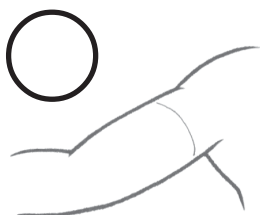
Request ■ When applying the BRACHIAL CUFF to one arm only, select "Right Bra. (or Left Bra.) + Both Ank.". For details, see "Entering Measurement Conditions" in "Patient Information Input" (page 45).

■ Position the BRACHIAL CUFF at a height equal to that of the patient's heart.

Note ■ If the patient has an irregular pulse, it may be impossible to measure accurately unless a regular pulse wave is obtained.

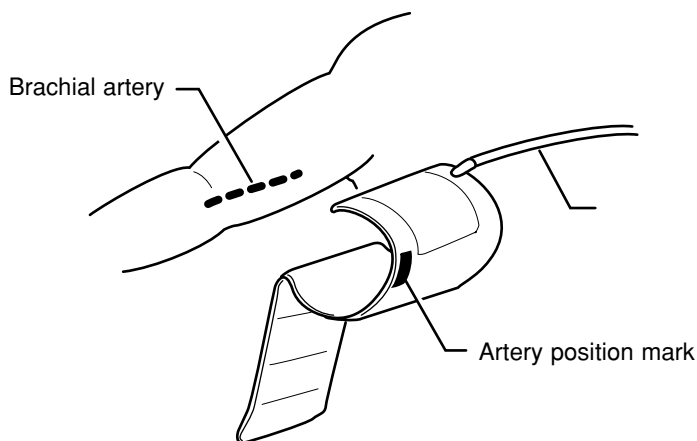
■ If there is shivering or cramping, an accurate pressure value may be impossible to obtain.

Caution! Wrap the cuff around a bare arm or thin clothing. Wrapping the cuff around thick clothing or rolled up sleeves may cause a large margin of error in the blood pressure measurement.



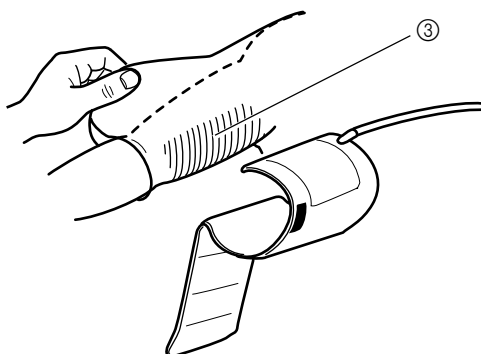
Proper cuff placement

1. When required, wipe the application site clean with diluted disinfectant alcohol. Place the patient in a supine position. The brachial artery runs down the inside of the arm. Attach the cuff so that the artery position mark aligns with the artery.

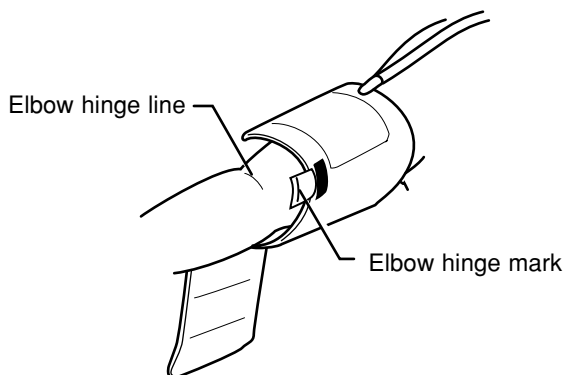


- When applying the cuff above clothing, pull the clothing so that it does not bunch up on the side of the artery ③.

If the cuff is wrapped around the arm with clothing bunched up at the artery site, the blood pressure will measure higher than the actual value.

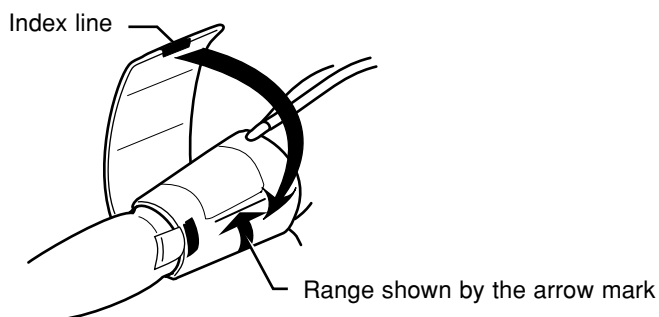


-
2. As a standard for deciding the up-down position, align the elbow hinge mark of the arm cuff with the elbow hinge line.

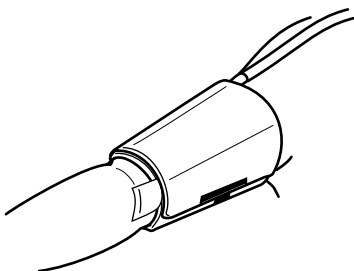


3. Wrap the cuff around the arm. At this time, be sure that the index line is inside the range shown by the arrow mark.

If the mark does not go inside the range, use a cuff of another size.



4. Wrap the cuff snugly so that 2 fingers can be placed between the cuff and the arm.



- Ensure there is no kink or closing of cuff and/or hose. When there is kink or closing in the cuff and/or hose, air is not let out from the cuff. This may result in bad blood circulation in the arm, causing peripheral functional disorder.

Application of the ANKLE CUFF

Cuff Selection

Choosing an appropriate cuff for the patient is necessary to get an accurate measurement. Choose a cuff appropriate for the patient according by referring to the table below. To attach to the CUFF HOSE, insert the hose and turn it clockwise to lock.

Name	Ankle circumference (cm)	Bladder width (cm)
CUFF No. 22, 23 Standard accessory	23 to 33	13
CUFF No. 25, 26 Standard accessory	16 to 25	10



Choose the appropriate cuff to avoid any error caused by gap between cuff and ankle in the measurements.

If the cuff used is too large, the blood pressure measurement may be lower than the actual value. If the cuff used is too small, the blood pressure measurement may be higher than the actual value.

Check that there is no looseness in the connection area. If there is an air leakage, correct measurements can not be taken.

Apply the ankle cuff to the ankle of the patient. The ANKLE CUFF are different for the right and left ankles. Be careful to attach the correct cuff with the correct location.

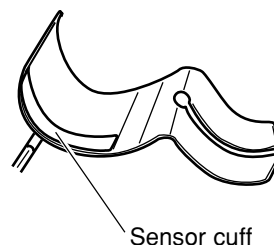
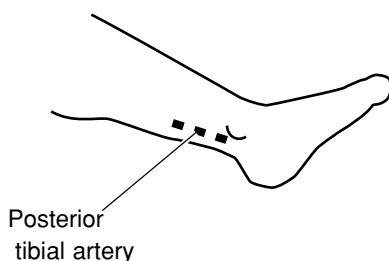


Do not use the ANKLE CUFF for patients that suffer from deep phlebothrombosis in the lower leg.

Note ■ If the patient has an irregular pulse, it may be impossible to measure accurately unless a regular pulse wave is obtained.

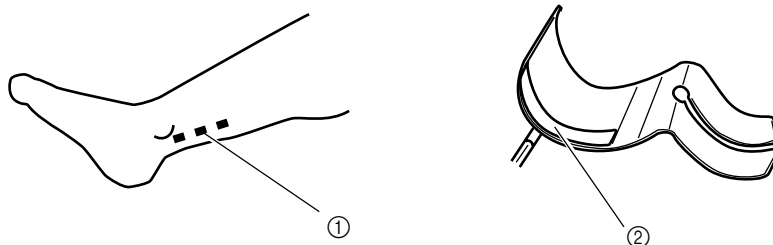
■ If there is shivering or cramping, an accurate pressure value may be impossible to obtain.

Caution! The dual chamber cuff has a special distal sensor cuff for the purpose of detecting the pulse. Wrap the cuff so that the sensor cuff is in contact with the posterior tibial artery of the ankle.

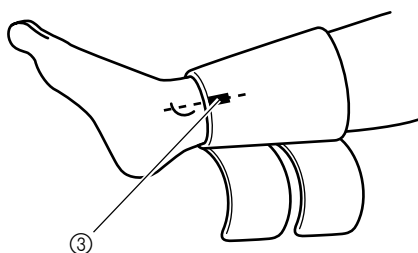


Proper cuff placement

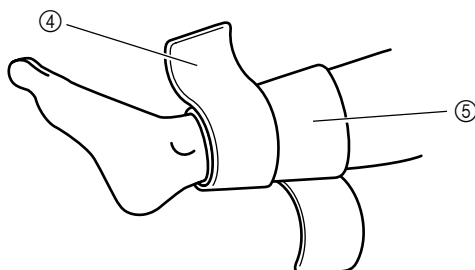
1. Remove socks or stockings. There are left ankle cuff and right ANKLE CUFF. Put cuffs on the correct ankle respectively. Put the hose area on the inside ankle. When required, wipe the application site clean with diluted disinfecting alcohol.
2. Apply the cuff to the ankle. Position the ankle cuff so that the sensor cuff ② on the inside is against the posterior tibial artery ①.



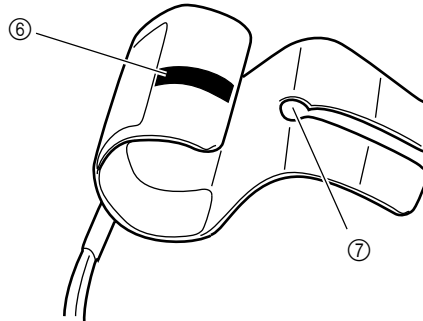
3. Align the mark at the bottom of the cuff ③ with the top of the ankle protrusion on the inside of the leg. Do not allow the cuff to lie over the ankle.



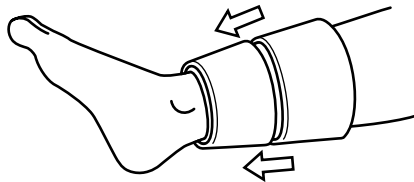
- If the cuff position shifts, the cuff will not detect the posterior tibial artery, and accurate measurement will be impossible. Be especially careful for patients with thin legs.
4. Wrap the belt on the ankle side ④, then wrap the calf-side belt ⑤. Allow enough slack to insert one finger between the leg and the cuff.



The ANKLE CUFF can be used to take the measurements of patients with an ankle circumference of 23 cm to 33 cm. If a section of the index line ⑥ can be seen through the cuff's window ⑦, that measurements can be taken.



5. Make sure the cuff does not shift downward. The cuff should stop at the top of the protruding ankle bone.



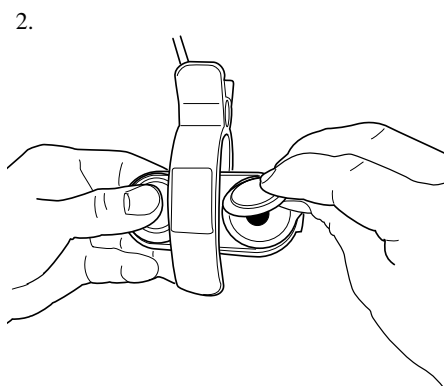
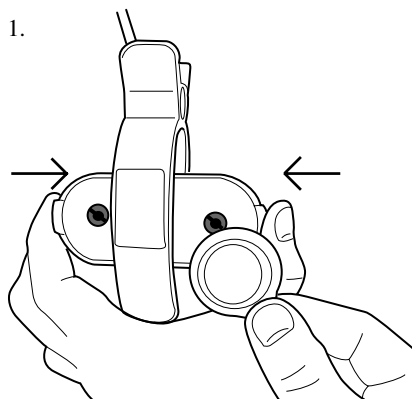
Application of ECG ELECTRODES CLIP

Apply the ECG ELECTRODES CLIP to the patient's wrists. There are different clips for the right and left arms. Do not apply the wrong one. When necessary, wipe the application site with diluted antiseptic alcohol or a similar product.

Attaching electrodes to ECG ELECTRODES CLIPS

Press and hold the button placed on the side of the ECG ELECTRODES CLIP and insert one electrode to the right ECG ELECTRODES CLIP. Release the button to fix the electrode to the clip. Repeat these steps with the left ECG ELECTRODES CLIP. Then, remove the protection sheets from all 3 electrodes.

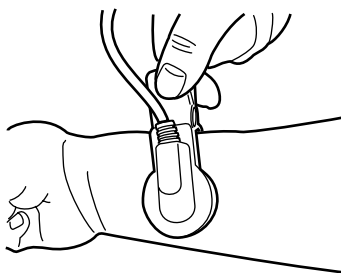
Use only Ag/AgCl type monitoring electrode.



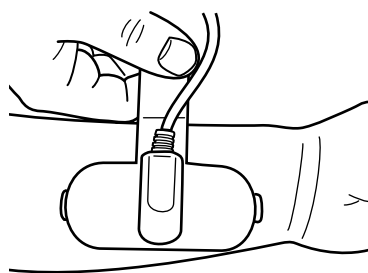
Application of ECG ELECTRODES CLIP

Application of electrodes:

- Do prep to the equipment surface as necessity.
- The sensor that has two electrodes is placed on the left side.
- Put electrodes on the inside of arms.
- Make sure to adhere electrodes closely.



Right ECG ELECTRODES CLIP
(with one electrode)



Left ECG ELECTRODES CLIP
(with two electrodes)



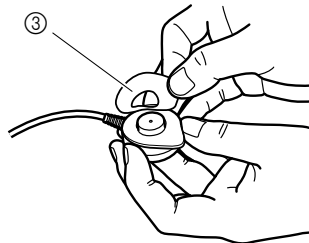
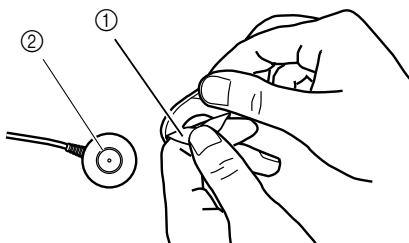
- It would be impossible to inspect STI because of mismonitoring of R-wave if the patient uses pace maker.
- It would be impossible to correctly inspect PWV and STI because of improper reading of waves, if the patient has medical history of arrhythmia.
- The conductive parts of ELECTRODES and associated connectors for APPLIED PARTS, including the NEUTRAL ELECTRODE, should not contact other conductive parts including earth.
- Even when reusing an ECG ELECTRODE CLIPS for the same patient, replace the electrodes with new ones every time if the skin is moist, injured, or infected.
- As a rule, the ECG ELECTRODE CLIPS are applied to both arms, but occasionally the ECG signal will be weak and measurement difficult. When this happens, place the electrodes for the left arm on top of those for the right arm (secondary induction) and measure.
- The expiration date for wrist electrodes is printed on their packaging. If the electrodes are used after the expiration date has passed, they may be dry, causing inaccurate measurement. Always use electrodes before their expiration date.
- **Cautions about ECG ELECTRODES**
 - If they are dry or worn, measurement cannot be operated accurately.
 - The wrist ECG ELECTRODE CLIPS electrodes are disposable. Re-use is possible only if they are being used on the same patient. Replace with new electrodes after application to the patient with damp, trauma, infection disease etc.

Application of PCG SENSOR

Preparation for PCG

Put (exchange) gel pad to PCG SENSOR.

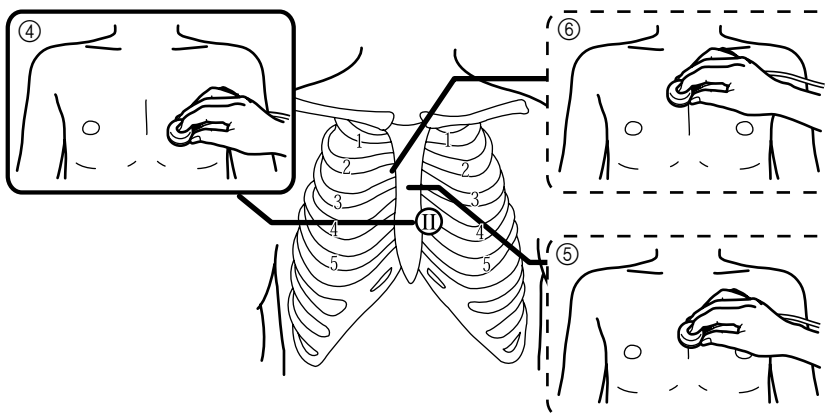
1. Take off the protective sheet ① (light blue) and put it to the sensor ②.
2. Strip clear cover sheet ③ which is on gel pad side.



Application of sensor

Pay attention to the following:

- Placement of PCG SENSOR is normally at the left edge of 4th-rib-case ④ as indicated below. Also, it is possible to place the sensor at the middle of the 3rd-rib-case ⑤. Or the right edge of 2nd-rib-area ⑥. Verify proper location by looking at the PCG indicator so that you can obtain the II sound.





- When patients have heart murmur or have abnormal sounds, accurate heart sound cannot be inspected.
- When patients generate noise during respiration, the sound cannot be inspected accurately.
- Do not drop the PCG SENSOR or PCG SENSOR WEIGHT on the patient. Doing so will cause injury.
- Cautions about gel pads
 - If they are dry or worn, measurements may not be taken accurately.
 - The PCG SENSOR gel pads are disposable. Reuse is possible only if they are being used on the same patient. Replace with new sensor gel pads after application to the patient with damp, trauma, infection, disease, etc.
- Even when reusing the PCG SENSOR part for the same patient, replace it with a new one every time if the skin is moist, injured, or infected.
- The expiration date for the PCG SENSOR part is printed on its packaging. If the sensor is used after the expiration date has passed, it may have dried, causing inaccurate measurement. Always use sensors before their expiration date.

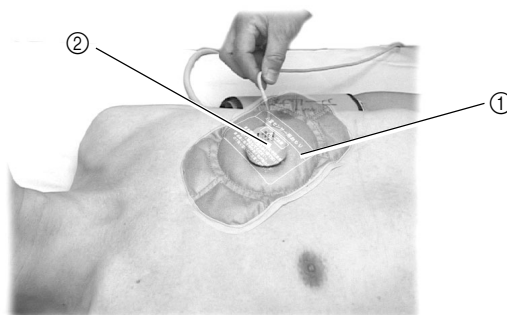
PCG Sensor Weight

Sometimes the screen does not display "PCG: OK" even when the PCG sensor position is changed. The following are likely causes of this:

- There is thick fat or muscle at the application site that attenuates heart sounds.
- The PCG SENSOR cannot adhere easily to the skin, due to excessive body hair.
- The PCG SENSOR cannot adhere to the skin, due to unevenness of the body surface.
- The PCG SENSOR adheres to the skin at a slant, because the body surface is not level.

These problems can be resolved by using the PCG SENSOR WEIGHT.

1. Place the PCG SENSOR WEIGHT ① over the PCG SENSOR ② from above, so that it covers the sensor.



- The PCG SENSOR WEIGHT can be placed over clothing.

Request

- Do not use a weight that has a hole or tear in its surface.
- If the filling of a weight leaks out, clean it up quickly.
- Be careful not to damage the surface of the weight with a ballpoint pen or other sharp-tipped object.
- If the weight is dampened by sweat or water, wipe it dry right away.
- Do not wash with water.

Measurement Information Input

After turning on the power and applying sensors, enter information about the patient.

The following patient information can be entered:

ID Number Enter up to 13 numeric characters that will be used for managing patient information.

Patient Information Enter patient information such as sex and height.

Measurement Conditions Enter necessary information related to measurement, such as the basic disease and measurement location.

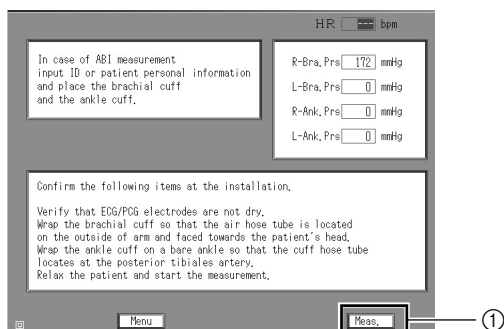
Take care to avoid mistakes in entering information and numerical values, because this information will be used when the analysis results are printed out.

ID Number Input

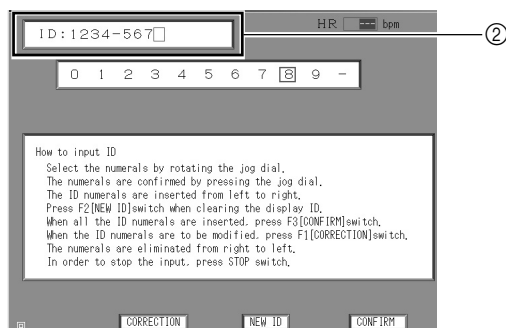
Enter up to 13 numeric characters that will be used for managing patient information. This section explains the procedure for entering new information.

- Note**
- Once a registered ID is entered, the associated name and other data can be retrieved from the CompactFlash memory.
 - You can also make settings that allow you to manage information using the ID number. For details see "User Setting" on page 79.

1. Press [Meas. (F3)] ①.



2. The ID Input Screen will be displayed. Enter an ID number for the patient.
Rotate the jog dial until the box highlights the number or letter you wish to enter (2), then push the jog dial to select.



- If you make a mistake, press [CORRECTION (F1)]. One character will be deleted from the right each time this is pressed.
 - To erase the patient ID, select [NEW ID (F2)] on the screen by pressing the function switch.
 - To return to the default values, press [Stop Switch].
3. When entry is finished, press [CONFIRM (F3)].

ID Number Input Conditions

- Up to 13 characters can be entered for the ID number.
Letters, numbers, and hyphens (-) can be used.
- ID Number Recognition

If you make a mistake in the number of characters when entering an ID number, it will be recognized as a different number. For example, "300" and "0300" are recognized as different IDs.

Patient Information Input

Enter patient information. The information to be entered is shown in area ① on the screen below.

①

ID: 1234-5678

HR bpm

SEX:

Male

HEIGHT: 165 cm (5' 05")

WEIGHT: ---. - kg (--- lb)

BIRTHDAY: JUN. / 15/ 1955
(Age: 51)

Meas. Part:Both Arms +Both Legs

Pressurized Right Ankle:AUTO

Pressurized Left Ankle :AUTO

Measurement Times: 1

Wait Time: 10 s

Tonometry : Carotid + Femoral

How to input HEIGHT and BIRTHDAY

1.Select the input items by rotating the jog dial located on the upper right corner of the unit.

2.Push the jog dial. The display is reversed and input the value by rotating the dial.

3.Press the jog dial once again to determine the value.

4.After inserting the HEIGHT and the BIRTHDAY. press F3 [CONFIRM]switch. Press STOP switch to stop the input.

AUTO Inflation

Low Inflation

CONFIRM

The following items can be entered:

- SEX

Enter the sex.
- HEIGHT

This is used when calculating PWV. Enter the correct height in centimeters. The entered height can range from 120 to 210.
- WEIGHT

This is used when calculating the BMI index. Enter in increments of 0.1 kg. The entered weight can range from 25.0 to 200.9. Weight input can be omitted.
- BIRTHDAY

Enter the month, day and year. When entry is complete, the patient's age are displayed.

Entering Measurement Conditions

Required information such as the measurement site can be entered here. The information to be entered is shown in area ② on the screen below.

ID: 1234-5678 HR bpm

SEX:

HEIGHT: 165 cm (5' 05")

WEIGHT: --- kg (--- lb)

BIRTHDAY: JUN. / 15 / 1955 (Age: 51)

Meas. Part: Both Arms + Both Legs

Pressurized Right Ankle: AUTO

Pressurized Left Ankle: AUTO

Measurement Times: 1

Wait Time: 10 s

Tonometry : Carotid + Femoral

How to input HEIGHT and BIRTHDAY

1. Select the input items by rotating the jog dial located on the upper right corner of the unit.
2. Push the jog dial. The display is reversed and input the value by rotating the dial.
3. Press the jog dial once again to determine the value.
4. After inserting the HEIGHT and the BIRTHDAY, press F3[CONFIRM] switch. Press STOP switch to stop the input.

The following items can be entered or selected:

Meas. Part

Select the default location for measurement. Normally "Both Bra. + Both Ank." is selected.

For patients who have an internal shunt for dialysis, the cuff will be applied only to the arm that has no shunt. Select either "Both Bra. + Left Ank." or "Right Bra. + Both Ank." for such patients.

When using an option such as a pulse wave unit TU-100 unit read the appropriate operation manual beforehand.

Pressurized Right Ank./Left Ank.

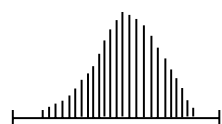
Normally "AUTO" is selected here. This system is set to inflate the cuff and measure the patient's blood pressure automatically. If the patient complains of pain caused by inflation, you can change to an already set lower value for the ankle by pressing [Low Inflation (F2)]. After that the pressure can be changed within the range of 100 to 280 by rotating the jog dial.

Note ■ If [Low Inflation (F2)] is pressed when the pressure upper limit item is selected, the set inflation value will be displayed. To return to the original value, press [AUTO Inflation (F1)].

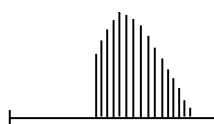
For more information about the inflation value setting, see "User Setting" (page 79).

Note ■ Set an appropriate upper limit for inflation, using "Maximum Pressure + 60 mmHg" as a guideline.

■ If the value entered as the upper limit for inflation pressure is not appropriate, the blood pressure measurement value will be low, as shown in the diagrams below.



a. Accurate measurement



b. Inaccurate measurement obtained when inflation is not sufficient

Measurement Times

The device automatically starts the next measurement cycle after waiting for the “Wait Time” to elapse.

Wait Time

This sets the period between the end of the first measurement and the start of the second measurement. The default is 10 seconds but this can be adjusted in the range of 10 to 120 seconds if necessary, in consideration of the patient's circulation.

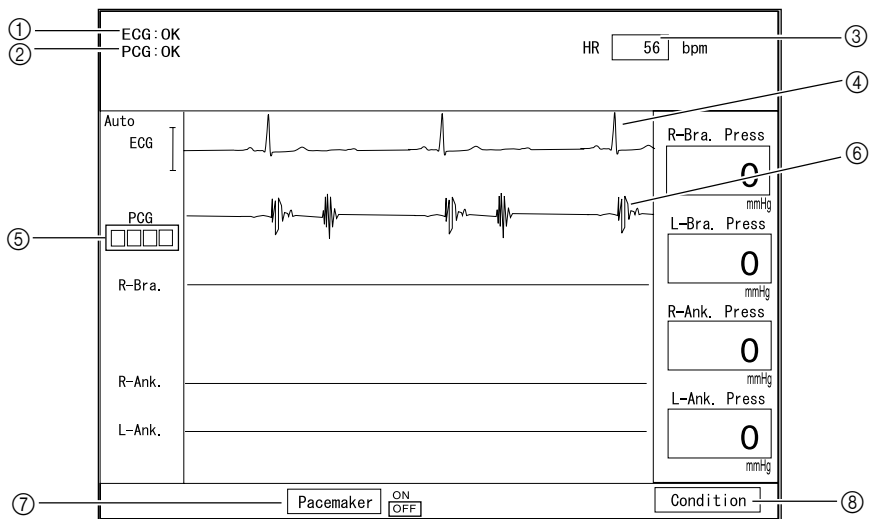
Tonometry

This item is valid when the pulse wave unit TU-100 set (only VP-2000) is installed. For information about this setting and the measurement procedure, see page 64.

Measurement Condition Input Procedure

1. Use the jog dial to select the item to be set.
2. Push the jog dial. The item will be highlighted.
3. Rotate the jog dial and select the desired numeral or selection.
4. Push the jog dial to confirm the selection.
5. Repeat steps 1 to 4 to make other settings.
6. When finished setting, press [CONFIRM (F3)]. The pulse wave display screen will appear.
To cancel settings before finishing, press Stop Switch.

Screen Display



① ECG Message

Displays the ECG status. For information about this display, see "ECG Messages" (page 48).

② PCG Message

Displays the PCG status. For information about this display, see "PCG Messages" (page 49).

③ Heart Rate

Displays the patient's heart rate.

④ ECG Wave

Displays the ECG wave. If this is not displayed, make sure nothing is disconnected. See "Application of ECG ELECTRODES CLIP" (page 38).

⑤ PCG Level

Displays the detected PCG level using four level meters. It is recommended that at least the third meter be flashing when measurement starts. Measurement can be performed even if only the second or lower meter is flashing, but accuracy may be reduced. When this happens, adjust the position of the PCG SENSOR or use the PCG SENSOR WEIGHT. See "Application of PCG SENSOR" (page 40).

⑥ PCG Wave

Displays the PCG wave.

⑦ [Pacemaker (F1)]

Press this, turning it ON, when the patient uses a pacemaker.

Note ■ When measurement is finished, the pacemaker setting is reset, returning it to OFF. Turn it ON each time measurement is performed.

■ The ECG display gain is normally set by an auto-gain function. However, when the pacemaker setting is turned ON, the gain becomes fixed at 10 mm/mV.

⑧ [Condition (F3)]

Changes the measurement conditions. This is displayed when "Simple Input: ON" is set.

ECG Messages

This section details the contents of the ECG messages. When "OK" is not displayed, measurement accuracy may be reduced. Take corrective action according to the content of the message.

Message Content	Status and Corrective Action
OK	ECG is stable. Measurement can begin.
Initializing	Checking the heart's electrical potential. Remain at rest.
Unstable R-R Interval	<ul style="list-style-type: none">• The electrodes are dry or dirty. → Replace with new electrodes (page 38).• The patient is tensing the arm, causing electromuscular effects. → Have the patient relax the arm and rest quietly.• Noise from radio interference is affecting the ECG waveform. → If a cell phone or other device is operating nearby, move it farther away.• Only a weak signal can be obtained from the wrist. → Try placing the ECG ELECTRODES CLIP from the left wrist on top of the one on the right wrist (secondary induction).
<ul style="list-style-type: none">• Check Electrodes• Check Patient / Electrodes• R-wave not Detected	<ul style="list-style-type: none">• No ECG ELECTRODE is placed in the ECG ELECTRODES CLIP. → Make sure that three wrist electrodes are securely placed (page 38).• The ECG ELECTRODE still has its protective cover. → Remove the protective cover from the ECG ELECTRODE (page 38).• An ECG CABLE is disconnected. → Make sure that all ECG CABLE are securely connected.

PCG Messages

This section details the contents of the PCG messages. When "OK" is not displayed, measurement will be impossible or accuracy may be reduced. Take corrective action according to the content of the message.

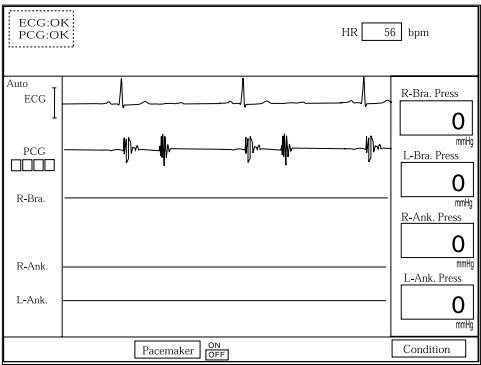
Message Content	Status and Corrective Action
OK	PCG is stable. Measurement can begin.
Initializing	Checking the heart sound. Remain at rest.
Signal Out of Range	<ul style="list-style-type: none">• The sensor has been touched, causing noise. → Remain at rest.• The PCG SENSOR is not adhering, or the shirt or other clothing has come under it. → Make sure the PCG SENSOR is correctly adhering to the skin. If correct adherence cannot be obtained, use the PCG SENSOR WEIGHT (page 41).• The PCG SENSOR pad is dry or dirty. → Replace with a new PCG SENSOR pad (page 40).• The PCG SENSOR has been applied upside down. → Apply the PCG SENSOR correctly.
Weak Signal	A position where three or more level meters are flashing is ideal. Measurement is possible even if two or less are flashing. However, accuracy of measurement may be reduced.
Re-position Sensor	<ul style="list-style-type: none">• Application site is not suitable. → Position the PCG SENSOR in a better location (page 40).• For patients with cardiac murmur or respiratory noise, it may be difficult to clearly distinguish the first and second heart sounds. While this may cause reduction in accuracy, measurement is still possible.
PCG Disconnected	<ul style="list-style-type: none">• The PCG cable is disconnected. → Make sure that PCG cable is securely connected.

Start of Measurement

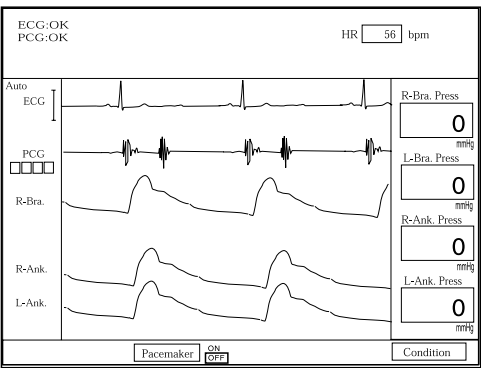
Measurement begins.

- Note** ■ Measurement ends after either one or two measurements. The second measurement is performed automatically under the following circumstances:
- When blood pressure cannot be accurately measured.

1. Check whether the screen display shows "ECG: OK" and "PCG: OK."



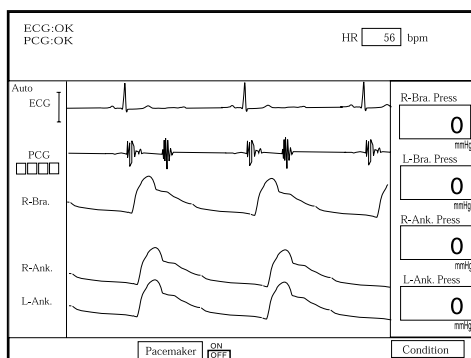
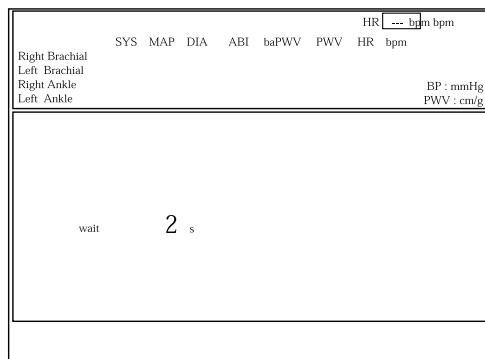
2. Press [Start Switch]. Measurement begins.



■ Performing second measurement

When first measurement is finished, a standby time counter is automatically displayed.

When the count is finished, the second measurement begins.



3. When the measurement is finished, the results are displayed on the screen, and the results are printed out.

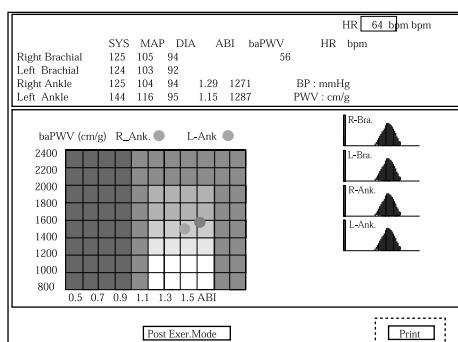
- If "No. of Print" is turned OFF, no printing will be performed. Results will be displayed on the screen only.

See "User Setting" → "No. of Print" (page 82).

- For the layout of the results screen, see page 53. For the layout of the inspection results sheet, see "Printing" (page 54).

■ Printing additional results

Use the jog dial to select the print sheet type from the results screen, then press [Print (F3)].



Note ■ When performing the recovery measurement after the continuous exercise measurement, press [Post Exer. Mode (F1)]. For details, see "Exercise Measurement" (page 57).

4. To end the measurement, press [Stop Switch].

Returns to the screen after the measurement.

The screenshot displays a setup screen with the following content:

HR: bpm

In case of ABI measurement input ID or patient personal information and place the brachial cuff and the ankle cuff.

R-Bra, Pres: mmHg
 L-Bra, Pres: mmHg
 R-Ank, Pres: mmHg
 L-Ank, Pres: mmHg

Confirm the following items at the installation.

Verify that ECG/PCG electrodes are not dry.
 Wrap the brachial cuff so that the air hose tube is located on the outside of arm and faced towards the patient's head.
 Wrap the ankle cuff on a bare ankle so that the cuff hose tube locates at the posterior tibiales artery.
 Relax the patient and start the measurement.

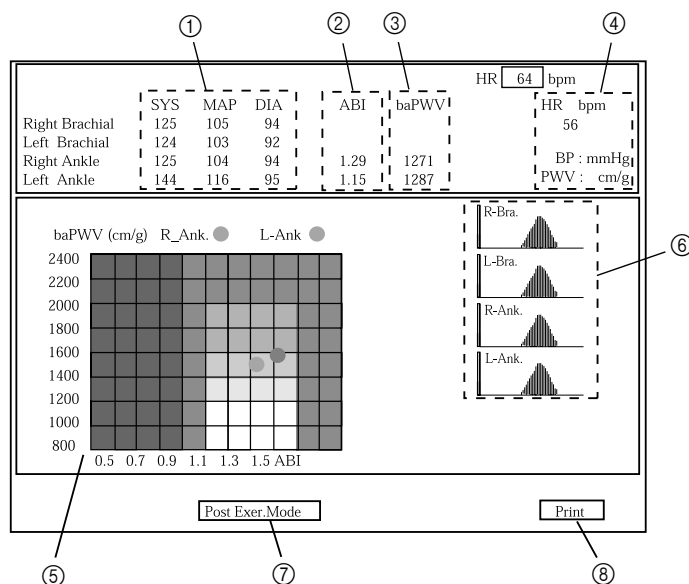
At the bottom, there are buttons for "Menu" and "Meas."

5. Remove the sensors from the patient.

Request ■ The ECG ELECTRODES CLIP and PCG SENSOR can be reused for the same patient. Do not use for another patient.

Results

This section describes the layout of the measurement results screen that is displayed when a measurement finishes. For information about printing out the measurement results, see "Printing" (page 54).



① Pressure measurement values

Displays the blood pressure values for each measurement part. The fields will be blank for any parts that were not measured. If the area could not be measured during the second measurement, the first measurement value will be displayed as is. If measurement was not successful both the first and second times, an error message will be displayed.

② ABI

Displays right and left ABI.

When blood pressure is measured at both arms, the ABI is calculated from the highest brachial pressure value.

③ baPWV

This displays the PWV value calculated from the time period from the start of the brachial pulse wave to the start of the ankle pulse wave.

④ HR

Displays the heart rate from the R-R interval obtained from ECG.

⑤ Graph

This graph shows the relationship between baPWV and ABI.

⑥ Simultaneous phase display line

This line expresses simultaneous phase measurement. If the time phases do not match due to remeasurement or other reasons, this line is not displayed.

⑦ [Post Exer. mode (F1)]

Press this when successive exercise measurements will be performed.

⑧ [Print (F3)]

Press this to print additional copies of the analysis result sheet. The number of copies can be set with the jog dial.

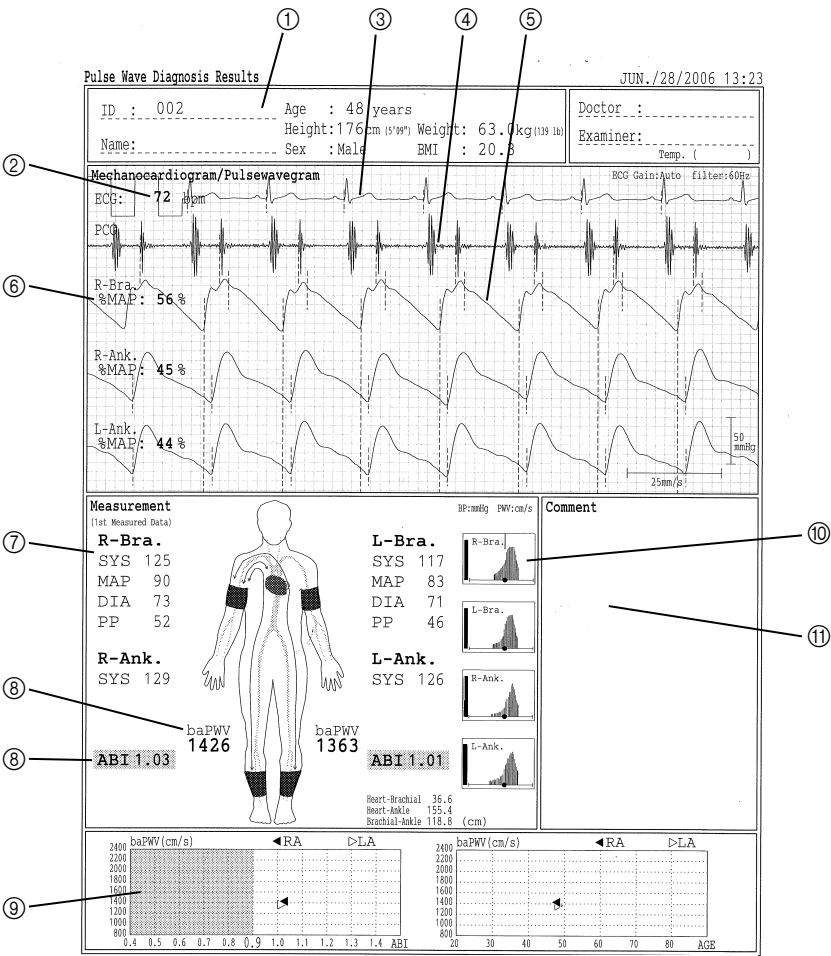


Do not turn off the power during printing. CF memory may be broken.

Printing

Standard

Prints the analysis results saved on the medical device that performed.

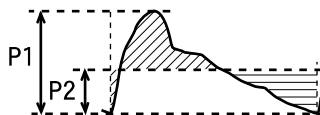


- ① Patient information
Shows the patient information entered into the patient information input screen.
- ② Heart rate
Shows the measured heart rate.
- ③ ECG
Printout of the ECG waveform.
- ④ PCG
Printout of the PCG waveform.
- ⑤ PVR waveform
Shows the pulse wave obtained from the measurement. Because the amplitude of these results is calibrated from the measured blood pressure value, the amplitude may be different than that shown on the screen.



⑥ %MAP

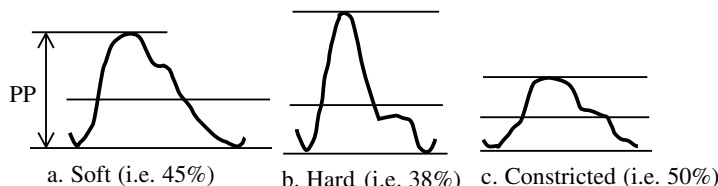
This value is one of the pulse waveform indexes that is calculated from the blood pressure values. It expresses, as a percentage, a value from the area of the wave form (P2) divided by the amplitude of the pulse (P1). This value is calculated with the following formula:

$$\%MAP = P2/P1 \times 100 (\%)$$



P1 : Pulse wave amplitude

P2 : Mean value of the area
(the level at which  and  are equal.)



⑦ Blood pressure values

The shows the blood pressure values for the left and right arm and left and right ankle. If measurement was not possible, a message will be displayed. For information about the contents of the message and corrective action, see "Error Messages" (page 88).



- When the blood pressure values for the right and left upper arms are greater than 16 mmHg, the highest blood pressure from the lower side is shaded.
- If a measured value is in parentheses, this indicates that it is a reference value only. This is because the accuracy of that value was low for some reason.

⑧ PWV

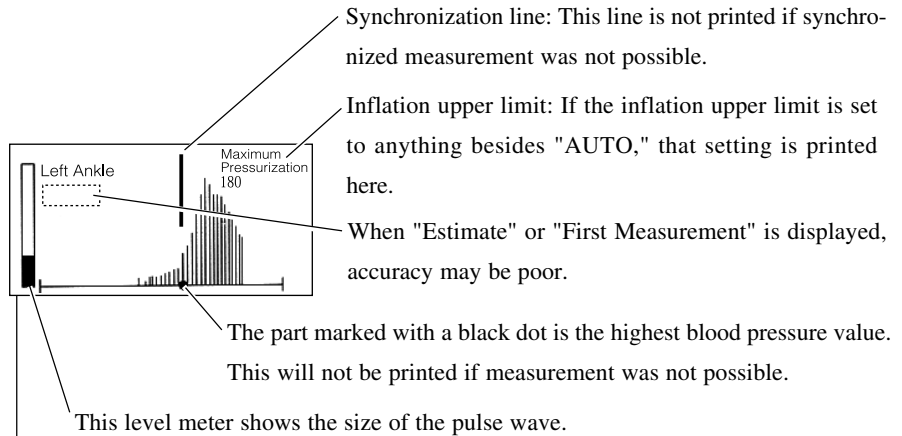
This gives the baPWV value. It measures the start of the brachial pulse wave to the start of the ankle pulse wave.

⑨ ABI value

Shows the right and left ABI values.

⑩ Pulsatile variation graph

This graph shows the pulsatile variation obtained from each cuff.



Border: when constriction of the upper arm or ankle is suspected, this border will be printed with a thicker line for emphasis.

⑪ Observation

Gives observations based on the test results.

Exercise Measurement

This function is used when the heart is given a set amount of exercise on a treadmill or similar device and then blood pressure is measured. After exercise is finished, the ECG and blood pressure gradually return to their status at rest. By measuring this process (recovery), abnormalities can be discovered that would be hidden at rest.



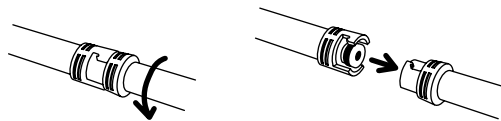
WARNING

- The amount of exercise given to the patient must be determined in consultation with a physician. Furthermore, during the exercise, always pay close attention to the patient's condition.
- When giving an exercise test to a patient with heart disease, a physician must attend and sufficient emergency measures must be prepared.

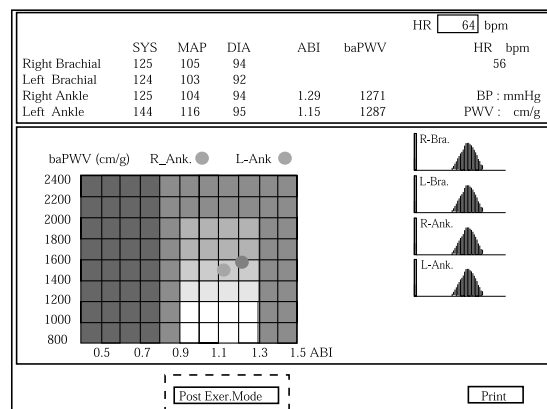
Note ■ Measurement can be performed for a maximum of 60 minutes after exercise.

Exercise Measurement Procedure

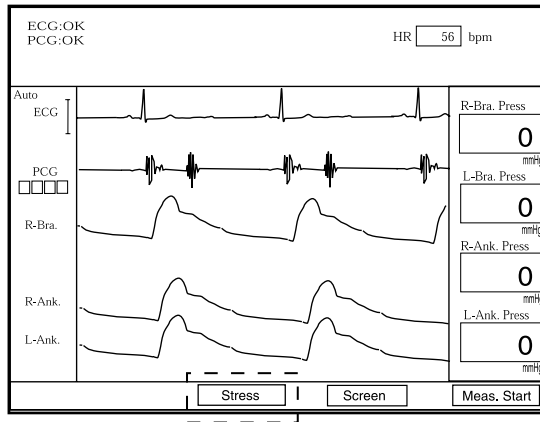
1. Take a normal measurement with the patient at rest (page 42).
2. Remove the ANKLE CUFF, ECG ELECTRODES CLIP, and PCG SENSOR from the patient.
 - The BRACHIAL CUFF can be left on the patient and disconnected from the CUFF HOSE as shown in the diagram below.



3. When the measurement results screen is displayed, press [Post Exer.Mode (F1)].



4. Set up the exercise. Press [Stress (F1)] to display the setup screen. The wave display screen will appear.



5. Select an exercise item using the jog dial, and input it. The exercise setup screen will be displayed.

The screenshot shows the same medical monitoring screen as before, but with a dashed rectangular box highlighting the input fields. The fields are: 'Distance' (with a unit 'm'), 'Degree' (with a unit '%'), 'Speed' (with a unit 'm/min'), 'Interval' (with a unit 'min'), and 'Meas. Part' (with a unit 'oth Arms + Both Legs'). The 'Stress' button is highlighted with a dashed box. The 'Screen' and 'Meas. Start' buttons are also visible at the bottom.

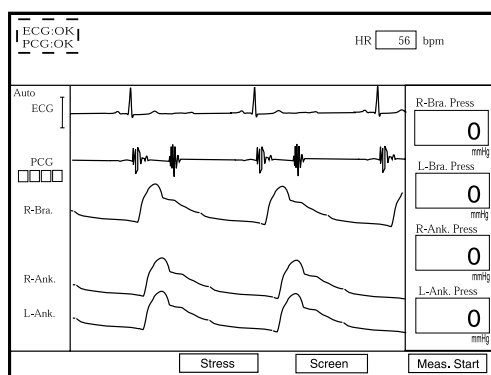
Note ■ The following items can be set:

- Distance
Enter the distance to be walked.
- Degree
Enter the treadmill's incline angle.
- Speed
Enter the treadmill's speed.
- Interval
Enter the measurement interval for after the exercise.
- Meas. Part
Enter the body part where blood pressure will be measured.

6. When entry is finished, press [Screen (F2)] to switch to the ECG/PCG wave screen.
7. Start the patient's exercise.
8. When exercise is finished, immediately apply the ANKLE CUFF, ECG ELECTRODES CLIP, and PCG SENSOR. Connect the BRACHIAL CUFF to the CUFF HOSE.
 - Connect the BRACHIAL CUFF to the CUFF HOSE as shown in the diagram below.

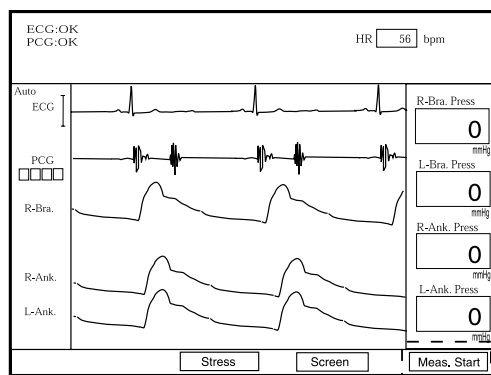


9. Check that "ECG: OK" and "PCG: OK" are displayed on the screen.



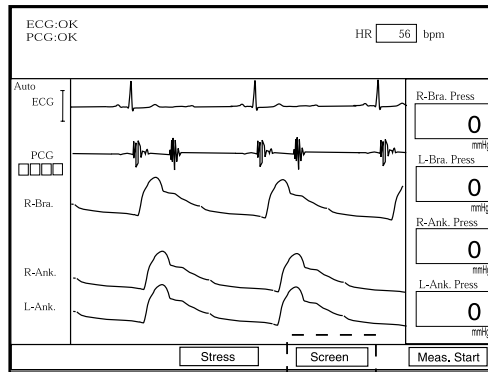
10. Press [Meas. Start (F3)] or Start Switch.

Measurement begins.



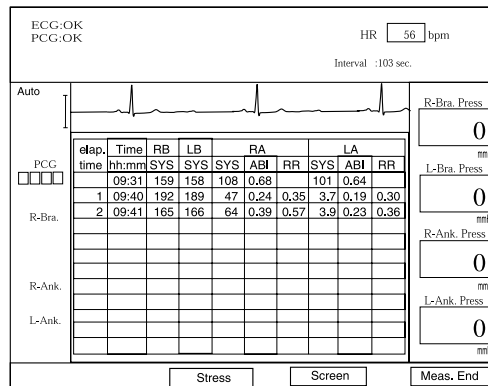
11. Press [Screen (F2)] to display the list screen.

For details on displaying this screen, see "Screen Display During Measurement" (page 61).



12. Check the "RR" (recovery ratio) value. If it exceeds 1.0, measurement will end.

Press [Meas. End (F3)].



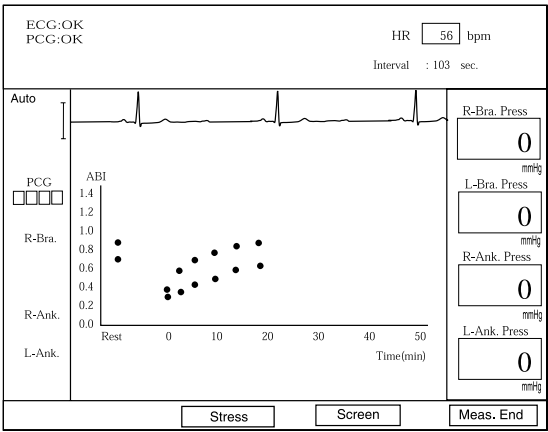
13. Press [End (F2)].

When measurement ends, the measurement results "recovery ratio" will be printed.

■ For details about "recovery ratio", see "Example of printout" (page 63).

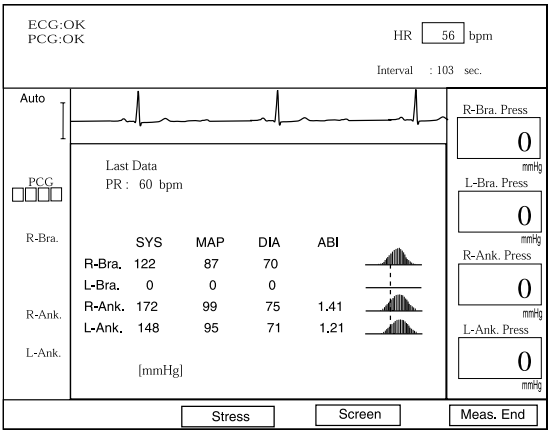
Trend screen

Graphs the trend of ABI values over the elapsed time.



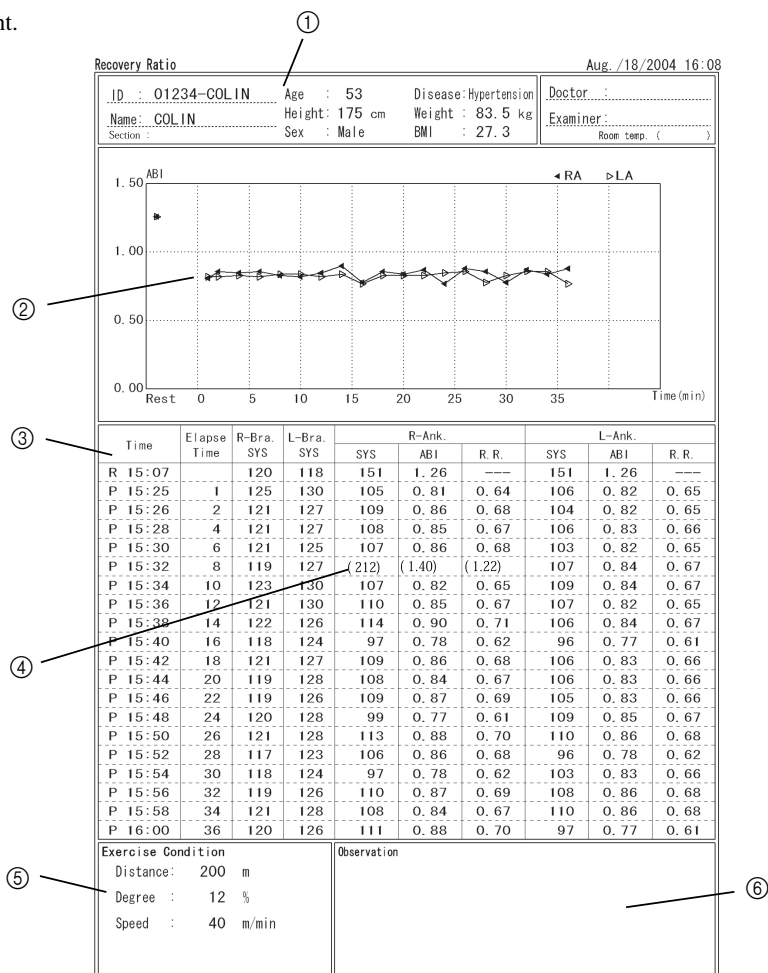
Previous data screen

Displays the most recently measured values and graphs the pulsatile variation.



Example of print-out

This device will automatically printout the results as follows, after completing the measurement.



① Patient information

Prints the patient information.

② Trend chart

Graphs the trend in ABI values over the elapsed time.

③ List data

Displays a list of measurement results, along with the elapsed time.

"R" in the "Measurement time" column indicates a measurement made at rest. "P" indicates a post-exercise measurement.

④ () shows unsuccessful measurement.

⑤ Exercise Condition

Prints information about the exercise conditions.

⑥ Comment

Prints remarks about the measurements.



Do not turn off the power during printing. CF memory may be broken.

Measurement Procedures VP-2000 (with tonometric sensor)

1. Sensor Attachment (except tonometry sensors)

Have the patient lay in the supine position, then attach the ECG ELECTRODES CLIPS, PCG SENSOR and the CUFF to the patient. (page 32)

2. Entering Information

Input the patient information and the measurement condition. (page 42)

Setting procedure for "Tonometry" is as follows;

The screenshot shows the VP-2000 device screen with the following fields and values:

- ID: 1234-678
- HR: [] bpm
- SEX: Male
- HEIGHT: 165 cm (5' 05")
- WEIGHT: --- kg (--- lb)
- BIRTHDAY: JUN / 15 / 1955 (Age: 51)
- Meas. Part: Both Arms + Both Legs
- Pressurized Right Ankle: AUTO
- Pressurized Left Ankle: AUTO
- Measurement Times: 1
- Wait Time: 10 s
- Tonometry: Carotid + Femoral

Below the input fields, there is a section titled "How to input HEIGHT and BIRTHDAY" with the following instructions:

1. Select the input items by rotating the jog dial located on the upper right corner of the unit.
2. Push the jog dial. The display is reversed and input value is shown.
3. Press the jog dial once again to determine the value.
4. After inserting the HEIGHT and the BIRTHDAY, press F [FIRM] switch. Press STOP switch to stop the input.

At the bottom of the screen, there are three buttons: "AUTO Inflation", "Low Inflation", and "CONFIRM".

Tonometry:

When the examination is conducted with using Tonometric sensor, select the type of Tonometric sensors.

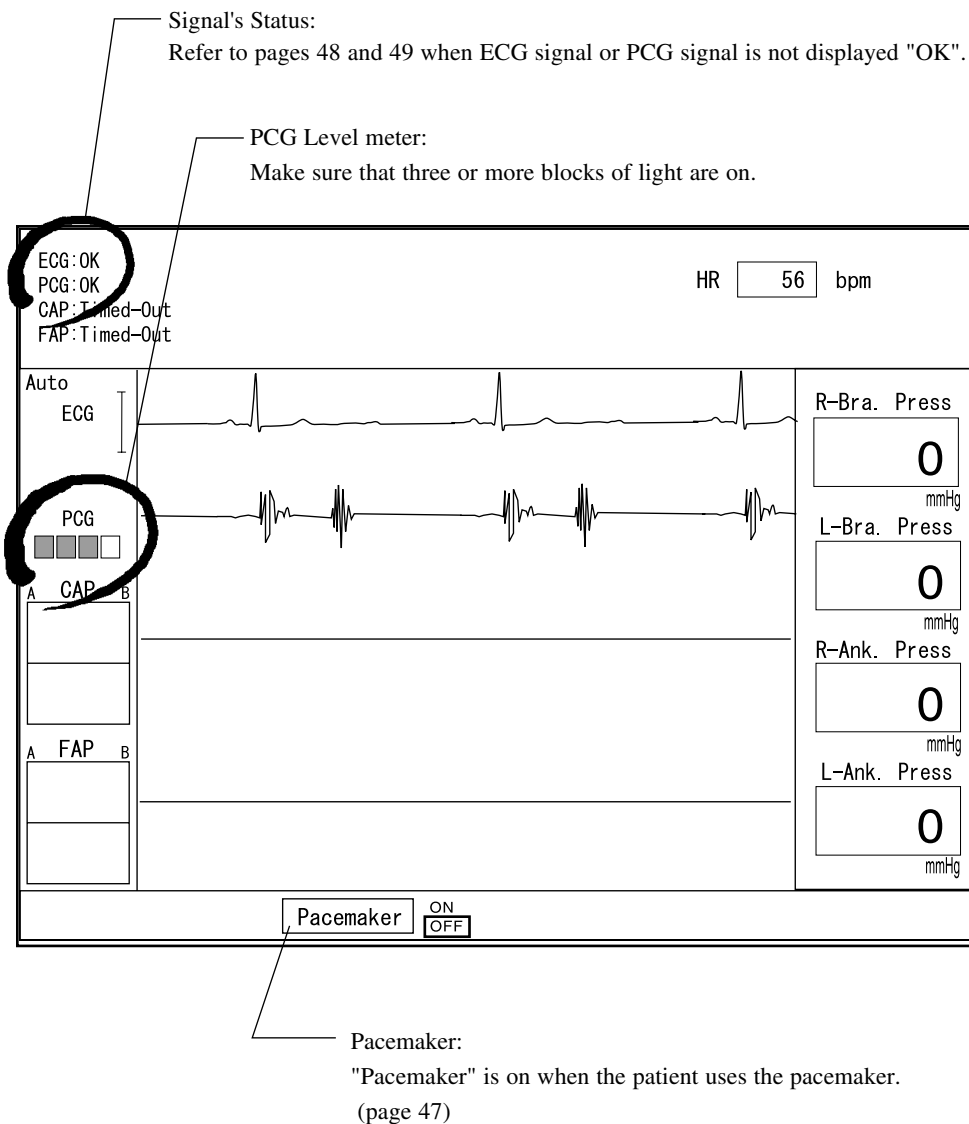
Blank No use of Tonometric sensor.

Carotid Only CAP sensor is used.

Carotid + Femoral ... Both of CAP sensor and FAP sensor are used.

3. Confirmation of ECG and PCG signals

Verify the stability of ECG and PCG signal on the following screen.



It is possible to start a measurement without the "OK" display, but the accuracy may be decreased.

4. Attaching the FAP SENSOR

FAP SENSOR is a optional and only when the sensor is selected in "User setting screen".

Feel for the pulse

Touch the femoral artery, and find a place where the pulse is easily felt.



Attach the sensor

Place the sensor on the area of the femoral artery found by touch above. Apply a constant pressure by hand while taking the measurement. The sensor should be applied directly to the skin.



- Apply a constant pressure while taking the measurement. This will have an influence on the precision of the measurement.
- If a patient is having convulsions or with a venous pulse, it may not be able to take a correct carotid pulse waveform.
- If a patient has an arrhythmia, the PWV may not be able to be correctly measured due to insufficient number of pulsation.
- The sensor head is made to be very precise and delicate. Applying undue strength or treating it roughly may cause damage.

Using the belt

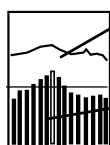
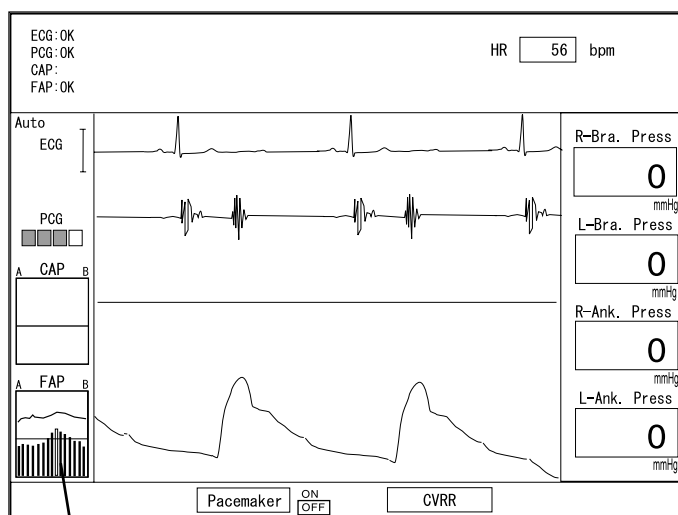
The belt can be used to hold the sensor in position. To use the belt, the belt loop has to be attached to the rear of sensor.



Stable, firm pressure can be obtained for the measurement by using the belt. The hold down pressure can be measured by the tonogram.

5. Confirmation of FAP signals

Check the stability of each signal.



Pressure:

The pressure as gained by each sensor element.

Tonogram:

Should ideally form a mountain shape. Yellow lines show the selected sensor elements. Attach the sensor so that the yellow lines are in the middle, insofar as possible.

If "OK" is not indicated at each signal's status, check the points below and make adjustments until the OK message is displayed.

Screen message	Countermeasure
FAP: Initializing	■ Please wait for a while.
FAP: Weak Signal	■ Change the attached position to the position with the strong pulse.
FAP: Ungetable Signal	■ Change the attached position of the sensor.
FAP: Time out	■ Check ECG.
FAP: Adjust Sliding Sensor Head FAP: Move sensor toward A-side FAP: Move sensor toward B-side	■ Reposition the sensor as instructed.

NOTE ■ The tonogram cannot be displayed when ECG electrodes are not attached to a patient.

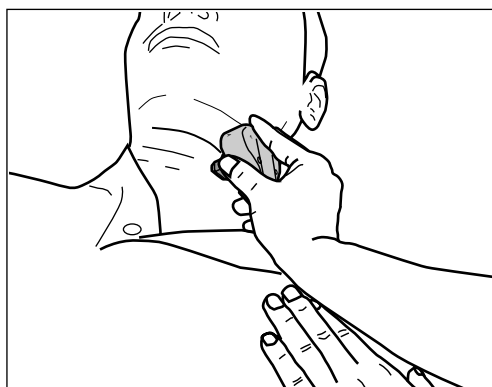
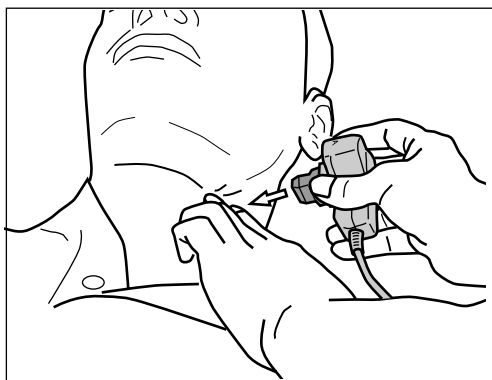
6. Using the Hand-held CAP SENSOR

When using the a Hand-held CAP SENSOR on the patient's neck, pay attention to the following:

- Do not use a pillow. The pulse will not be properly detected.
- Palpate the neck to find the pulse, then place the sensor on the area where the pulse was found.
- The sensor should be applied to the left side of the neck.
- Apply the sensor with gentle pressure and a steadied/supported hand to eliminate motion artifact.

Apply the sensor according to the following instructions:

1. Palpate the neck to locate the area where the pulse can be found.
2. Place the sensor with the transducer over the carotid pulse, applying steady gentle pressure.
3. The sensor should not touch the tendons or Adam's Apple.



WARNING

- The CAP SENSOR detects the pulse wave through user applied pressure to the neck. Do not use it for purposes for other than a short examination.

CAUTION

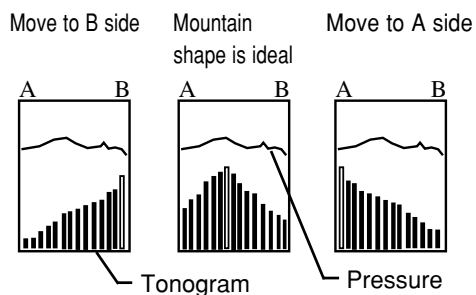
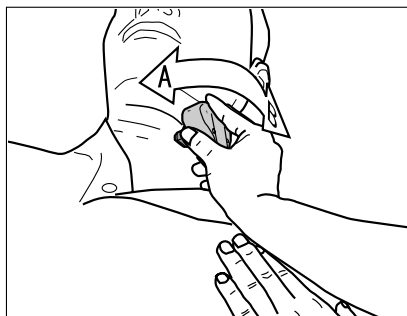
- If a patient is having convulsions, and/or with a venous pulse, it may not be able to take a correct carotid pulse waveform.

Checking the attachment

Fix the position of sensor by checking the tonogram on the screen. Adjust the position of the sensor to make the tonogram a mountain shape.

Adjustment of the position

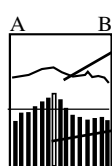
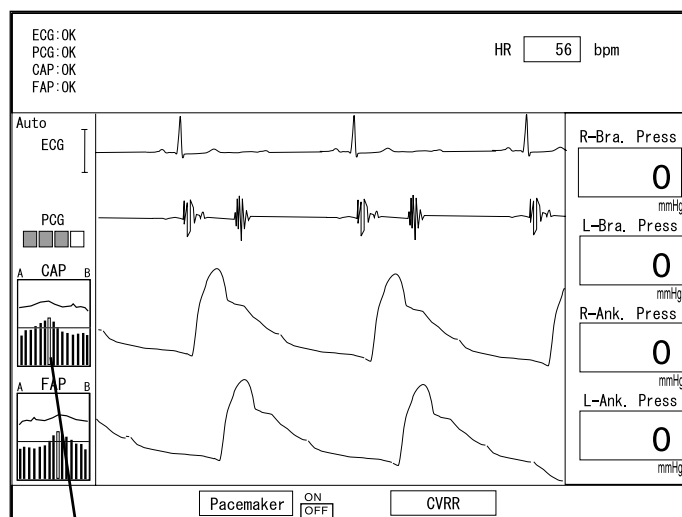
When the message "Move to A side" or "Move to B side" is shown, move the sensor in the indicated direction and re-attach it.



The sensor head is made to be very precise and delicate. Applying undue strength or treating it roughly may cause damage.

7. Confirmation of CAP and FAP signals

Check the stability of each signal.



Pressure:
The pressure as gained by each sensor element.

Tonogram:
Should ideally form a mountain shape. Yellow lines show the selected sensor elements. Attach the sensor so that the yellow lines are in the middle, insofar as possible.

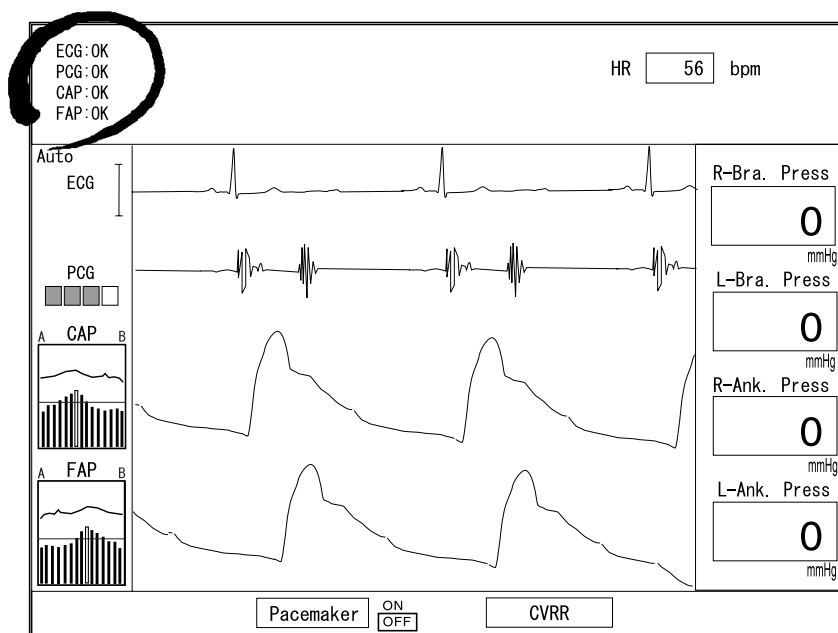
If "OK" is not indicated at each signal's status, check the points below and make adjustments until the OK message is displayed.

Screen message	Countermeasure
CAP: Initializing	■ Please wait for a while.
CAP: Weak Signal	■ Change the attached position to the position with the strong pulse.
CAP: Ungetable Signal	■ Change the attached position of the sensor.
CAP: Time out	■ Check ECG.
CAP: Adjust Sliding Sensor Head CAP: Move sensor toward A-side CAP: Move sensor toward B-side	■ Reposition the sensor as instructed.
CAP: Weak Spring Pressure CAP: Strong Spring Pressure	■ Change the pressure adjustment lever of the sensor

- NOTE**
- The contents of the messages for the FAP SENSOR are the same as those for the CAP SENSOR.
 - The tonogram cannot be displayed when ECG electrodes are not attached to a patient.

8. Start Measurement

Select "Start" on the screen by the function switch, once "OK" is displayed. Alternatively, you can start the measurement by the start switch on the main unit.



WARNING

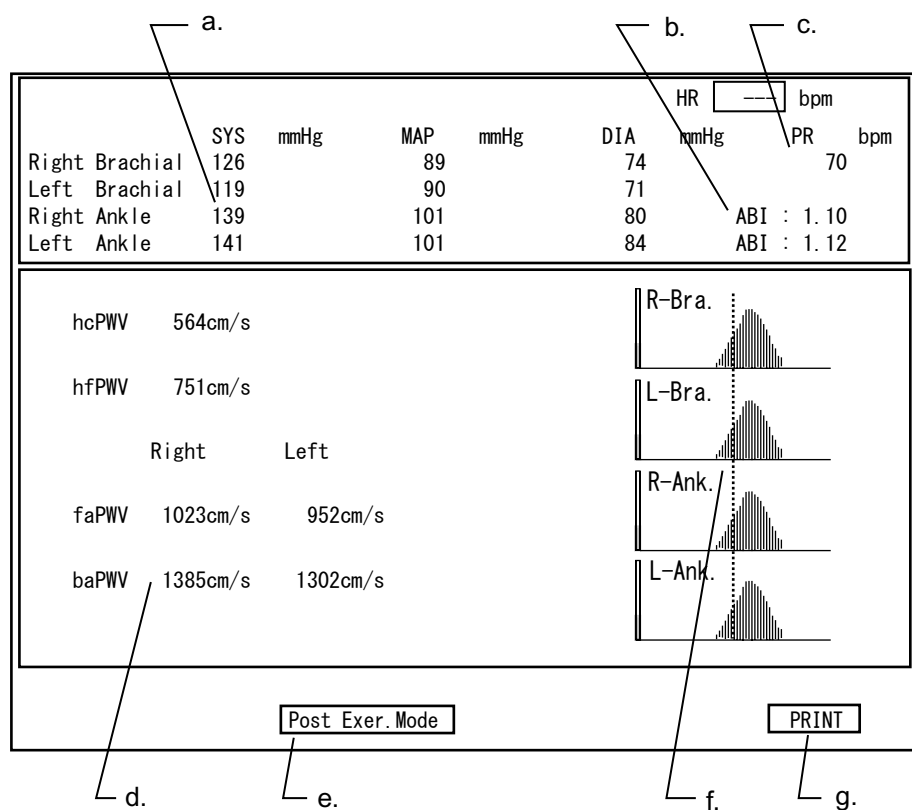
- CAP SENSOR puts pressure on the neck and detects the pulse waveform. Do not use it for any purpose other than brief examination.
- After the sensor is attached, a patient may feel sick, pain, deterioration of pulse or become unconscious. Keep checking the conscious level and the condition of a patient, and proceed with the examination, following the doctor's instruction.
(Be careful of carotid sinus syncope and carotid sinus reflex allergens.)

CAUTION

Measurement can be started even when "OK" is not indicated, however, in that case, the measurement analysis result may not be accurate.

9. Completion of Measurement

1. After the completion of the blood pressure measurement, the results will be displayed. See the display example as follows:
2. Disconnect the sensors and cuffs from the patient.
3. The results will automatically be printed. See the example of the printout as found on the following page.
4. Press “Stop” switch to return the initial screen and examine the next patient.



-
- a. Blood pressure data: when there was no measurement, the display will show ---. When the measurement could not be taken, the error message will be displayed. The error message will also be indicated on the printout. (page 73)
 - b. ABI data: the higher brachial systolic BP will be used for the calculation when both arms are measured.
 - c. Pulse rate: the pulse rate is obtained from the brachial cuff (Right).
 - d. This is the result of the analysis. hcPWV is displayed at "PWV".
 - e. Select "Post Exer. mode" by the function switch to start ABI measurement after the exercise test. (page 57)
 - f. Synchronized measurement line: this line indicates that all the four blood pressures were taken at the same phase, which means that all the systolics were measured at the same time. This line will be not shown when all BPs were not measured at the same phase, e.g. upon on cuff measurement retry.
 - g. The test result will be printed once automatically after the measurement. Select "PRINT" by the function switch when you need additional copies.
-



Indicates before the measurement or the measurement has failed.

345

Blue back and yellow number indicates that the measurement is outside of the range listed under "Specifications".

Caution! Take actions immediately when following alarms set off during measurement.

1) R-Wave Not Detected

HR of ECG signal cannot be counted. Check a patient's condition. If the patient is in normal condition, check whether ECG clip and ECG electrode are placed correctly on the patient.

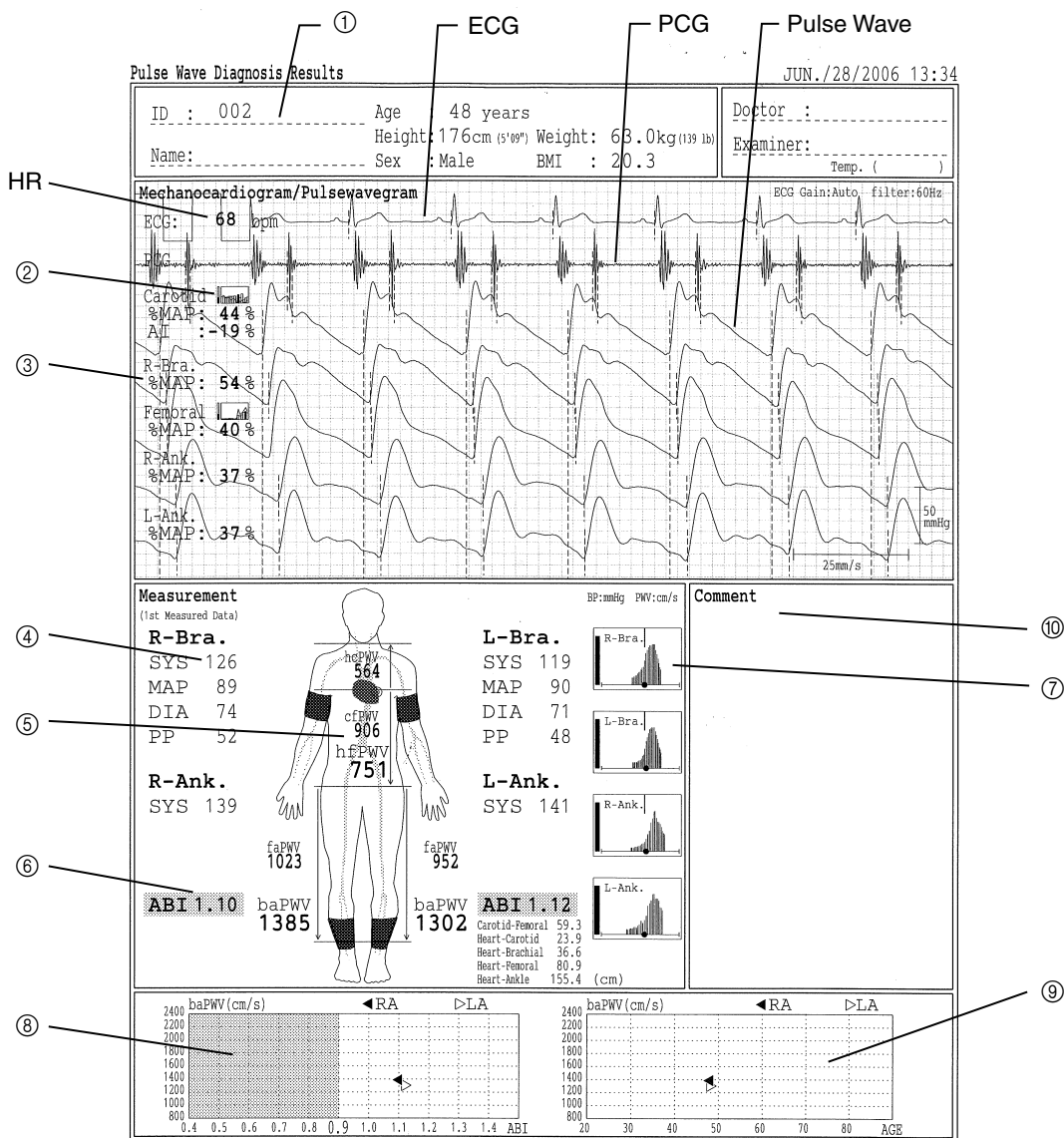
2) SYS<=70mmHg

The numerical indication of systolic blood pressure on the screen is reversed. (Yellow character on black.)

Check a patient's condition. If the patient is in normal condition, check whether cuffs are placed on correctly and measure again.

Example of a printout

An example of the printout below gives explanations of the diagnosis results.



① Patient name

Shows the patient information entered into the patient information input screen.

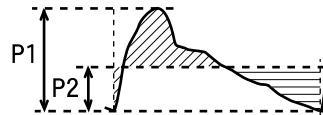
② Tonogram

Information from the tonometry sensor elements.



③ %MAP

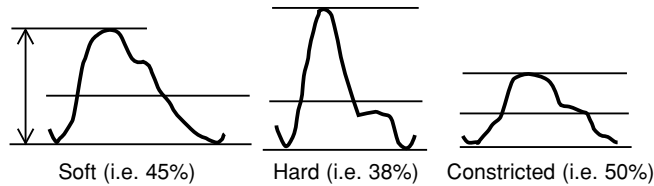
This value is one of the pulse waveform indexes that is calculated from the blood pressure values. It expresses, as a percentage, a value from the area of the wave form (P2) divided by the amplitude of the pulse (P1). This value is calculated with the following formula:

$$\%MAP = \frac{P2}{P1} \times 100 (\%)$$

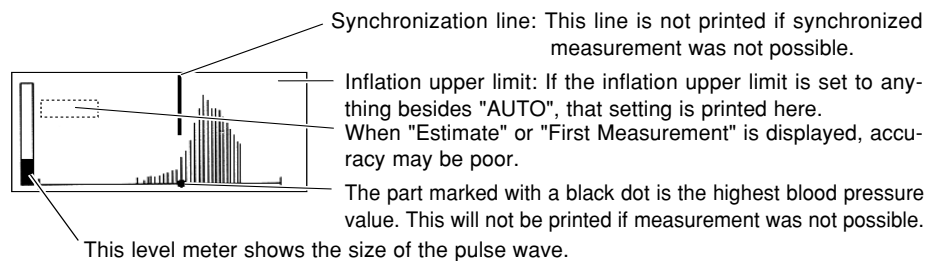


P1: Pulse wave amplitude

P2: Mean value of the area
(the level at which  and  are equal.)



- ④ This area shows each blood pressure measurement result. If a measurement could not be taken, an error message will be recorded. (Refer to page 88.) When the difference of systolic blood pressure between right brachial and left brachial is 15 mmHg or greater, the lower of the data is printed with a shaded background.
- ⑤ This area shows each PWV data.
- ⑥ Right and left ABI.
- ⑦ Oscillometric envelope obtained by each cuff.



- ⑧ The baPWV value is plotted on the y-axis and the ABI value on the x-axis of this graph.
- ⑨ The baPWV value is plotted on the y-axis and the age is plotted on the x-axis of this graph.
- ⑩ The error message, if any, will be printed here.

Settings

If you press [Menu (F1)] in the initial screen displayed after power is turned ON, the menu screen is displayed. In this screen you can make basic device settings, and process past test data.

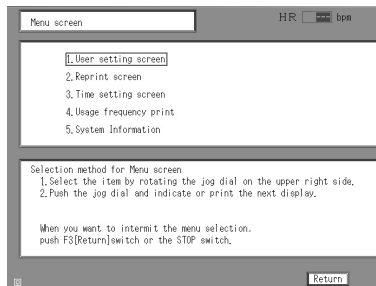
Menu Screen

This section describes the menu screen and the operations that can be performed there.

Procedure

This section gives the procedure for making menu selections. There are two menu types, one that displays another screen when a selection is made from the menu and one that prints a document titled after the menu selection.

1. Rotate the jog dial on the menu screen.
As you rotate the dial, the selection box moves down the menu.
2. Use the box to highlight the menu item you wish to select, and push the jog dial. Another screen will be displayed or a document will be printed.



- To cancel without making a selection, press [Return (F3)] or Stop Switch.

Menu Contents

The table below shows the menu contents.

	Name	Contents	Page Reference
1	User Setting Screen	Sets numerical values and functions involving checkup.	Page 79
2	Reprint Screen	Prints data for the past 10 measurements.	Page 83
3	Time Setting Screen	Sets the default date and time for this device.	Page 84
4	Usage Frequency Print	Prints a "Usage Frequency Report."	Page 85
5	System Information	Lets you check version information for the system software used by this device.	Page 86

User Setting

Sets numerical values and functions involving checkup. Use the jog dial to make selections and settings.

User's Settings		HR bpm
Distance	: 200 m	Meas. Part : Both Arms +Both Legs
Degree	: 12 %	Meas. Times : 1
Speed	: 40 m/min	Wait Time : 10 s
Recorder Speed	: 25 mm/s	ABI Base : OFF
Stiffness	: OFF	STI : ET/PEP
Stiffness Comm	: ZONE	No. of Print:
ID Control	: ON	Std Pt Trend
Low Inflation	: 100	1 1 1

How to input User setting screen

1. Select the input items by rotating the jog dial located on the upper right corner of the unit.
2. Push the jog dial. The display is reversed and input the value by rotating the dial.
3. Press the jog dial once again to determine the value.
4. After inserting the Function Data, press F3[CONFIRM] switch.

CONFIRM

1. Rotate the jog dial on the user setting screen.
As you rotate the dial, the selection box moves down the menu.
2. Use the box to highlight the menu item you wish to select, and push the jog dial.
The item will be highlighted.
3. Rotate the jog dial to select the item content.
4. Push the jog dial.
Confirms the item you have set.
5. Repeat steps 1 to 4 to set other items.
6. When setting is finished, press [CONFIRM (F3)].
The display returns to the screen menu.
To cancel settings before finishing, press Stop Switch.

Functions That Can Be Set

Exercise Volume Input values for walking distance, walking degree, and walking speed to determine the patient's exercise load.

Recorder Speed Selects the sweep rate for the pulse wave diagram.

Selection	Contents
25 mm/sec	Sets the sweep speed at 25 mm per second.
36 mm/sec	Sets the sweep speed at 36 mm per second.

Stiffness When Pulse Wave Diagnosis Results (#1) is selected, this setting determines whether "Stiffness" diagrams will be included.

Selection	Contents
ON	Include stiffness levels.
OFF	Do not include stiffness levels.

Stiffness Comm This setting determines whether arteriosclerosis (baPWV) comments will be printed in the Pulse Wave Diagnosis Results (#1).

Selection	Contents
Zone	Display three levels, "Average", "High" and "Low".
%	Use numerals to display a percentage.

ID Control Selects whether to manage patients using ID control.

Selection	Contents
ON	Enables ID number control. When an ID number is entered, this selection is used to retrieve patient data saved in CompactFlash memory under the same ID. This allows measurement to begin for frequently measurement repeat patients without having to reenter patient information each time. Only the patient ID number need be entered for measurement to begin.
OFF	Disables ID number control. Set this when doing group measurement or when there is no need for ID numbers. IDs can be entered, they will be recognized as numbers for individual measurements only.

Low Inflation This sets the inflation value used to when [Low Inflation (F2)] (page 45) is pressed while entering measurement conditions.

Meas. Part

This sets the default values for blood pressure measurement parts displayed for "Meas. Part" on the patient information input screen.

When using options (such as the Pulse Wave Unit TU-100), review the operation manual for each one.

Selection	Contents
Both Arms + Both Legs	Measure at both Arms and both Legs.
Both Arms + Right Leg	Measure at both Arms and right Leg.
Both Arms + Left Leg	Measure at both Arms and left Leg.
Right Bra. + Both Legs	Measure at right brachial part and both Legs.
Right Bra. + Right Leg	Measure at right brachial part and right Leg.
Right Bra. + Left Leg	Measure at right brachial part and left Leg.
Right Bra.	Measure at right brachial part.

Meas. Times

Select "2" for the simultaneous blood pressure measurement of 4 limb.

Wait Time

When making simultaneous measurements (refer to page 46), you can set interval between the measurements.

ABI Base

This sets the base ABI value that determines whether a second measurement will be performed.

Selection	Contents
(Number Value)	Set an ABI default value in the range of 0.30 to 1.30. When the ABI value in the measurement results is lower than the value set here, a second measurement will be automatically performed regardless of the setting for synchronized measurement.
OFF	Do not use the base ABI value to judge whether to perform a second measurement.

STI

This selects the formula for actuating the STI ejection index.

Selection	Contents
PEP/ET	Calculate with PEP/ET
ET/PEP	Calculate with ET/PEP

No. of Print

Sets the number of copies printed for "Standard", "Patient" and "Trend" Pulse Wave Diagnosis Results.

Selection	Contents
OFF	Do not print.
(Numerical Value)	Set the number of copies to print, from 1 to 10.

Note ■ When not using a printer, set the number of copies for "Standard", "Patient" and "Trend" to "OFF".

Reprint

This function lets you print data from past measurements and edit patient information.

- Note** ■ The past data that can be retrieved from this screen consists of the last 10 items going back from the most recent.

Reprint screen

HR bpm

	ID	Sex	Age	Date	Time
1	001	Male	50	2006/ 5/10	10:29
2	001	Male	50	2006/ 5/ 9	11:49
3	001	Male	50	2006/ 5/ 9	11:19

How to input Reprint results

1. Select the Data by rotating the jog dial.
2. After The Selection. Press F3[PRINT] switch to print.
3. After The Selection. Press F2[DELETE] switch to delete.
4. Press F1[ALL PRN] switch to print all the Displayd Items.
Press the STOP switch to return to Initial Display.

ALL PRN

DELETE

PRINT

Reprinting

■ Printing only one item

1. Select the Data by rotating the jog dial.
2. After The Selection. Press F3[PRINT] switch to print.

■ Printing all

1. Press F1[ALL PRN] switch to print all the Displayed Items.

Deleting Patient Information

1. Select the Data by rotating the jog dial.
2. After The Selection. Press F2[DELETE] switch to delete.

- Note** ■ If you wish to stop printing while print all is in progress, press Stop Switch.

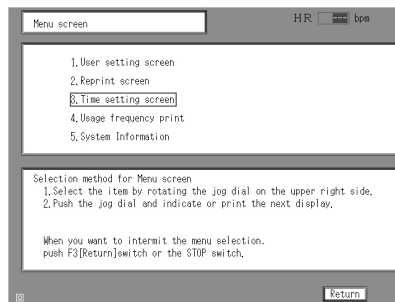
Time/Date Setting

This sets the standard time and date used by this device.

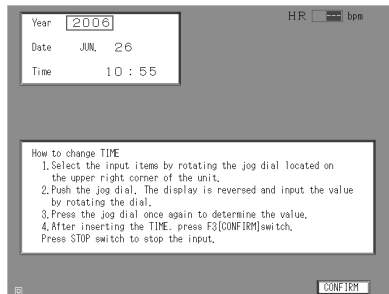
The time and date settings of the device are already set when the machine is delivered. Use the procedure below to change them.

1. On the menu screen, select "3. Time Setting Screen."

The Time/Date Setting Screen will be displayed.

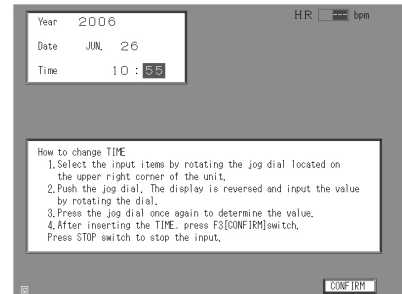


2. Place the box over the item you wish to select, and push the jog dial.



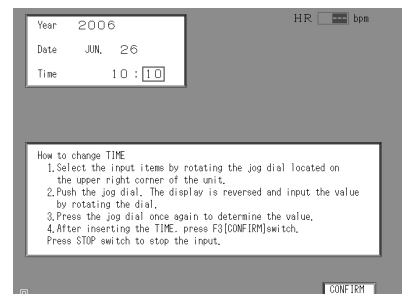
The changeable part of the item will be highlighted.

3. Rotate the jog dial and select the item contents.



4. Push the jog dial.

The item contents are set.



5. Repeat steps 2 to 4 until all settings are made.
6. When finished setting, press [CONFIRM (F3)].

The display returns to the screen menu.

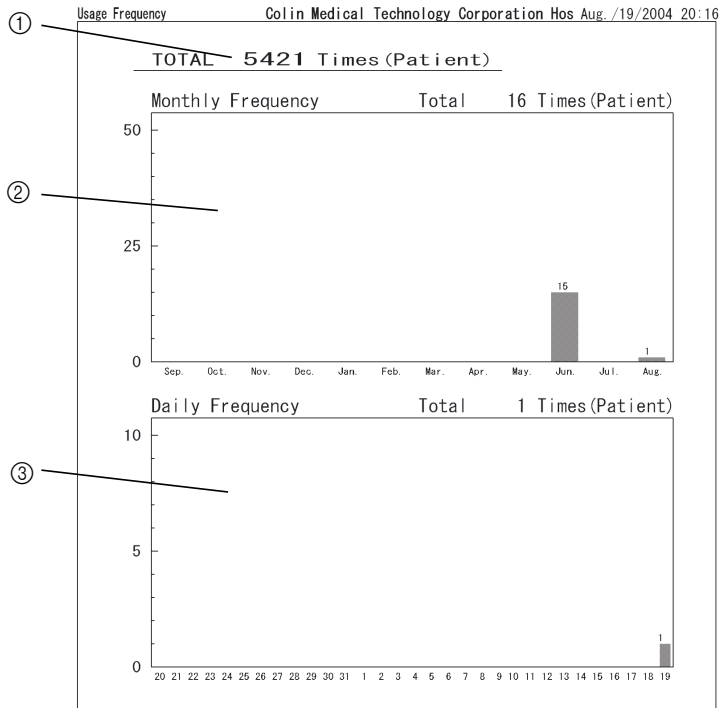
To cancel settings before finishing, press [Stop Switch].

Usage Frequency Report

Prints the "Usage Frequency Report".

Usage Frequency Report

This function lets you check past usage frequency.



① TOTAL Times

Prints the total number of measurements performed.

② Monthly Frequency

Graphs the frequency of usage over the last month.

③ Daily Frequency

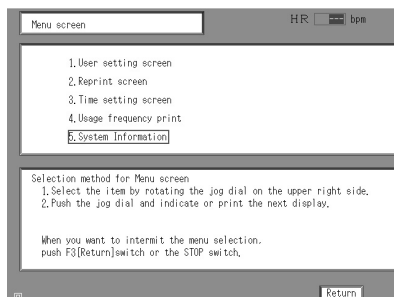
Graphs the frequency of usage over the last day.

System Information

You can use this item to check the version information for the system software used by this device.

1. Select "5. System Information" on the menu screen.

System information is displayed.



Note ■ You will be asked to provide this information if you contact Colin for customer service.

Maintenance

Troubleshooting

Cannot Print Correctly

This section gives possible reasons and corrective actions that apply when the measurement results will not print correctly. Reprint the document that did not print from the menu screen.

Cannot Print

CAUSE	Corrective Actions
The power switch on the printer is turned OFF.	Turn ON the printer power switch.
No paper is loaded. ("Form Feed" on the printer is flashing.)	Load paper in the printer.
The printer is not connected correctly.	Check the cable connecting the printer.

Text and graphics print faintly

The toner supply is nearly exhausted. Replenish the toner.

Paper jams

Paper is jammed inside the printer. Remove the paper jam.

Using damp paper, the back of paper that has already been copied, or binder paper with holes in it will cause paper jams. Do not use such paper.

Error Messages

If an error occurs before measurement or during the measurement process, an error message is displayed. In addition, an error message will be printed in the test results if the measurement could not be accomplished successfully. This section explains the cause of error messages and corrective actions that can be taken to resolve them.

If the symptoms do not improve even after the corrective actions described here are taken, turn OFF the power switch and contact the person in charge of servicing the device.

■ Error Message Types

Error messages can be divided into three categories, based on their importance.

An alarm (highest priority) sounds and the error message is displayed.

An alarm that goes "...beep-beep-beep...beep-beep..." sounds repeatedly. A serious problem has occurred in the device, or some type of abnormality may have occurred in the patient. No measurement can be made in this state. The content of the error must be investigated.

An alarm (medium level) sounds, and an error message is displayed.

An alarm that goes "...beep...beep...beep..." sounds repeatedly. A problem has occurred that makes measurement difficult. The content of the error must be investigated.

An error message is displayed

An error has occurred that will make it difficult to obtain correct measurement results. Investigate the content of the error.

■ Error messages that sound an alarm (highest priority)

Message Contents	Cause and Corrective Actions
RAM Check: S-ERROR RAM Check: D-ERROR ROM Check: ERROR MSR Board: ERROR Internal Error API Internal Error	An internal problem has been detected in this device. Turn OFF overall power to the system and turn it ON again. If this action does not change the content of the message, repairs are required. Contact the person in charge of servicing the device.
API Communication Error	An internal communication error has occurred. Check the following items, then turn OFF the power switch and turn it ON again. <ul style="list-style-type: none"> • Is power to the API unit turned ON? • Are connectors for the cables between the units properly connected?
API DC Voltage Error	The power supply voltage for the cuff control unit has dropped. Check the following items, then turn OFF the power switch and turn it ON again. <ul style="list-style-type: none"> • Make sure the outlet the power cord is plugged in has sufficient capacity. Do not use multi-line distribution blocks or low-rated (thin) extension cords. • Do not share the outlet with devices, such as laser printers or copiers, that temporarily draw large amounts of current.
No Signal from Sensor Cuff	The pulse wave detected at the ankle sensor cuff was too small to be recognized. <ul style="list-style-type: none"> • If the cuff is too loose, reapply it. • If the cuff has been applied over a thick sock or other garment, reapply it after removing the garment. • Make sure the cuff signal cable to the API unit is not disconnected. If the cable is reconnected, the power supply switch must be cycled OFF, then ON again.
Measurement Results are highlighted in red	The highest blood pressure measurement was 70 mmHg or below. <ul style="list-style-type: none"> • If the patient has low blood pressure, take appropriate action. • If the patient has an obstruction in the brachial area, use the other arm to determine the central blood pressure. • Measure with the cuff positioned at the same height as the heart.
R-wave Not Detected	Cannot detect R wave. <ul style="list-style-type: none"> • First check the condition of the patient. • Check that the electrodes are correctly applied. • Make sure the electrodes are not old or dry. • Make sure the patient's skin is not dirty.
Check Patient/Electrodes	An ECG error has been detected. <ul style="list-style-type: none"> • First check the condition of the patient.
	The electrodes are not correctly applied, or the circuit is saturated by offset voltage. <ul style="list-style-type: none"> • Check that the electrodes are correctly applied. • Make sure the electrodes are not old or dry. • Make sure that the protective sheet has been removed. • Make sure the patient's skin is not dirty.

■ Error messages that sound an alarm (medium priority)

Message Contents	Cause and Corrective Actions
During measurement, the following is displayed: "The measurement area setting and the applied cuff may be different. Check before starting measurement".	<p>The cuff inflation speed was not appropriate.</p> <ul style="list-style-type: none"> • Make sure the application site setting matches the actual cuff type. For details, see "Patient Information Input" (page 44) and "Entering Measurement Conditions" (page 45).
"Unconnected Cuff Hose [1]" is displayed during measurement.	<p>The required pressure cannot be achieved even though the pump is activated.</p> <ul style="list-style-type: none"> • Make sure the pump hose has not become disconnected. • Make sure the BRACHIAL CUFF or ANKLE CUFF is applied at the correct location. • Check for looseness in the cuff.
	<p>The cuff or cuff hose is worn out or damaged.</p> <ul style="list-style-type: none"> • Replace with a new cuff or cuff hose.
"Check Memory Card Insertion" is displayed in the initial screen.	<p>Power was turned ON with no CompactFlash memory installed.</p> <ul style="list-style-type: none"> • Turn OFF the power, insert the CompactFlash memory, then switch power ON again. <p>To continue measurement with no CompactFlash memory installed, press the [Stop Switch]. No patient information or measurement data will be recorded.</p>
"Read Error", "Write Error", or "Memory Card Data Failure" is displayed on the initial screen:	<p>An attempt to read data from the CompactFlash memory failed.</p> <ul style="list-style-type: none"> • Turn OFF the power switch, then switch it ON again. If the same error is displayed, internal data may be corrupted. It may be possible to recover the internal data. Contact the person in charge of servicing the device.
"Memory Card Cover is Open" "Open"	<p>The cover for the CompactFlash insertion port is open.</p> <ul style="list-style-type: none"> • Close the cover. If measurement is performed with the cover open, entered patient information and measurement results cannot be recorded.
"Memory Card Full" "Full"	<p>The CompactFlash memory is full.</p> <ul style="list-style-type: none"> • Turn OFF the power and replace with a new CompactFlash memory. • Turn OFF the power switch, remove the memory, and copy the patient information to another media. Erase the patient information in the card and replace in the device.

CAP / FAP**Sensor Failure****ERROR TYPE**

System Error

ALARM TYPEMedium Priority,
Latched,
Mute Enable

CAUSE	COUNTER-MEASURE
A sensor cannot be initialized. A sensor may be out of order.	Turn off the power, and change a sensor for a new one. When it is difficult to change a sensor, call our customer service. If a sensor is not necessary for measurement, press Alarm Mute so that measurement can be continued.

Sensor Temperature Error**ERROR TYPE**

System Error

ALARM TYPEHigh Priority,
Latched,
Mute Unable

CAUSE	COUNTER-MEASURE
Proper measurement cannot be taken due to low room air temperature.	Power on again after keeping the room air temperature at 15°C.

Check Cable Connection**ERROR TYPE**

System Error

ALARM TYPEMedium Priority,
Latched,
Mute Enable

CAUSE	COUNTER-MEASURE
A different type of a sensor is connected.	Turn off the power, and connect a correct sensor. If a sensor is not necessary for measurement, press Alarm Mute so that measurement can be continued.

Excessive FAP pressure**ERROR TYPE**

Technical

ALARM TYPEMedium Priority,
Latched,
Mute Enable

CAUSE	COUNTER-MEASURE
The FAP sensor is pressing against the measuring device with more pressure than is necessary.	Reduce pressure.

Excessive CAP pressure**ERROR TYPE**

Technical

ALARM TYPEMedium Priority,
Latched,
Mute Enable

CAUSE	COUNTER-MEASURE
The CAP sensor is pressing against the neck with more pressure than is necessary.	Reduce pressure. (Actions such as swallowing may cause temporary activation of this error.)

CAUTION!

Impact on the patient increases when the pressure rises. Ensure that the device is positioned correctly and conduct measurements with the least amount of pressure possible.

CAP Sensor Communication Error**FAP Sensor Communication Error****ERROR TYPE**

System Error

ALARM TYPEHigh Priority,
Latched,
Mute Unable

CAUSE	COUNTER-MEASURE
Communication with a sensor has been interrupted. There is a possibility that a sensor plug may be pulled out of TU-100 connector, or a sensor may be out of order.	Check whether a sensor is properly connected, then turn on Power again. At that time, if Carotid / Femoral cannot be selected in Menu-User Setting Screen-ATP MODE, a sensor is possibly out of order. Turn off Power, then change a sensor for a new one. Measurement that does not use a sensor can be continued.

Weak Signal

ERROR TYPE
Technical

ALARM TYPE
No sound,
Low Priority,
Non-Latch

CAUSE	COUNTER-MEASURE
Detected signal is not strong enough for accurate analysis.	Change an attached position of a sensor in order to obtain a stronger signal. If necessary, change an angle of a sensor head, a length of arm, a strength of spring and so on for CAP sensor, in accordance with a patient.

Unstable ECG Signal

ERROR TYPE
Technical

ALARM TYPE
No sound,
Low Priority,
Non-Latch

CAUSE	COUNTER-MEASURE
R wave of ECG signal is unstable.	Refer to ECG status display.

Unstable Signal

ERROR TYPE
Technical

ALARM TYPE
No sound,
Low Priority,
Non-Latch

CAUSE	COUNTER-MEASURE
Pulse waveform is fluctuating.	Tell a patient to stay still. If a waveform fluctuates even when a patient stays still, change a position of Sensor in order to obtain a stable waveform. If necessary, change an angle of a sensor head, a length of arm, a strength of spring and so on for CAP sensor.

ECG R-wave Not Detected

ERROR TYPE
Technical

ALARM TYPE
No sound,
Low Priority,
Non-Latch

CAUSE	COUNTER-MEASURE
Necessary R wave of ECG signal, as a trigger for analyzing pulse waveforms, cannot be detected.	Check whether ECG signal is obtained correctly.

Adjust Sliding Sensor Head

ERROR TYPE
Technical

ALARM TYPE
No sound,
Low Priority,
Non-Latch

CAUSE	COUNTER-MEASURE
Pressure on a sensor head is not appropriate.	Change an angle of a sensor or the position.

Move Sensor toward A (B) -side

ERROR TYPE
Technical

ALARM TYPE
No sound,
Low Priority,
Non-Latch

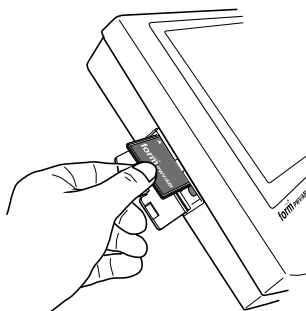
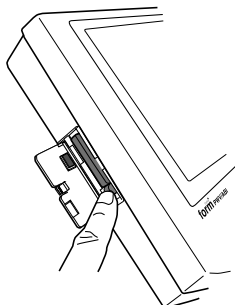
CAUSE	COUNTER-MEASURE
A position of a sensor head is not adjusted in the center of artery.	Move a sensor head toward A (B)-side.

■ Removing the CompactFlash Memory

If the CompactFlash memory is removed, the contents of the user setting screen will return to their default values. When the CompactFlash memory has been reinstalled, check the contents of the user setting screen and change the settings as needed.

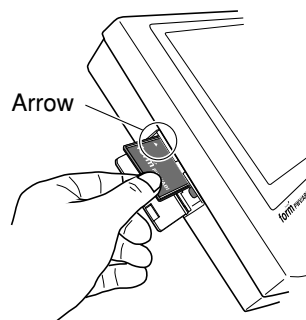
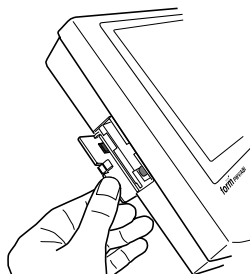
1. Turn OFF the power.
2. Open the cover on the side of the main unit, and press the card eject button.
3. Remove the CompactFlash memory.

● Do not touch the metal parts.



■ Installing the CompactFlash Memory

1. Make sure power is turned OFF.
2. Open the cover on the side of the main unit.
3. With the arrow on its side facing upward, insert the CompactFlash memory card in the slot until the eject button comes out with a click.



4. Close the cover on the side of the main unit.

■ Other Error Messages

Message Contents	Cause and Corrective Actions
Motion Artifact [2]	<p>Could not measure because the patient moved frequently during measurement.</p> <ul style="list-style-type: none"> • Have the patient rest quietly during measurement. <p>When simultaneous measurement has been set, two successive measurements will be performed. To stop measurement, press the Stop Switch.</p>
Check Cuff/Patient [3]	<p>Blood pressure cannot be measured because the pulse signal is weak.</p> <ul style="list-style-type: none"> • If the cuff is applied over a thick sock or other clothing, remove the garment and reapply the cuff. <p>When simultaneous measurement has been set, two successive measurements will be performed. To stop measurement, press the Stop Switch.</p>
Noise Interference [4]	<p>Could not measure blood pressure because the patient moved or pressure was applied to the outside of the cuff.</p> <ul style="list-style-type: none"> • Have the patient rest quietly during measurement. • Make sure no outside pressure is applied to the cuff. <p>When simultaneous measurement has been set, two successive measurements will be performed. To stop measurement, press the Stop Switch.</p>
	<p>Measurement was interrupted because it continued more than 160 seconds. If the cuff inflation is not sufficient because the patient has pseudo-high blood pressure caused by calcification, measurement might not be possible.</p>
Insufficient Cuff Pressure [5]	<p>Could not sufficiently inflate the cuff. Pressure could not be well detected because the patient moved or pressure was applied to the outside of the cuff.</p> <ul style="list-style-type: none"> • Have the patient rest quietly during measurement. • If the cuff is applied over a thick sock or other clothing, remove the garment and reapply the cuff. • Make sure no outside pressure is applied to the cuff. <p>When simultaneous measurement has been set, two successive measurements will be performed. To stop measurement, press the Stop Switch.</p>
Measurement values are displayed in blue on a white background	<p>A measurement value was detected that exceeded measurable range.</p> <ul style="list-style-type: none"> • Use the heartbeat graph to see if the measurement was performed correctly. <p>If the graph is not normal, check cuff application and the patient's status, then remeasure.</p>
Unstable R-R interval	<p>An unstable R wave interval was detected. Noise entered the signal because the patient moved.</p> <ul style="list-style-type: none"> • Have the patient rest quietly during measurement.
	<p>Noise entered the signal because of severe arrhythmia or patient convulsions. If there is severe arrhythmia, measurement accuracy may be poor. Judge the results after reading any error messages displayed after measurement.</p>
Signal Out of Range	<p>The signal is too strong and the circuit may be saturated.</p> <ul style="list-style-type: none"> • Check the application positions of the sensors, and reposition them correctly.

Message Contents	Cause and Corrective Actions
Weak Signal	<p>The detected signal is too weak. Measurement is impossible.</p> <ul style="list-style-type: none"> • Check the application positions of the sensors, and reposition them correctly.
	<p>The sensor could be broken.</p> <ul style="list-style-type: none"> • If there is no change in the signal display even if the sensor is touched with a finger, contact the person in charge of servicing the device.
Re-Position Sensor	<p>Strong noise has entered the signal, such as from vibrations in the area.</p> <ul style="list-style-type: none"> • Remeasure in a quieter location.
"Analysis Not Available" displayed after measurement	<p>Required data not obtained in analysis, could not analyze.</p> <ul style="list-style-type: none"> • Refer to the displayed message, and remeasure.
"Verify Analysis for Accuracy" displayed after measurement	<p>Due to noise effects, the minimum number of heartbeats required for analysis was not reached. Only low-accuracy data was obtained.</p> <ul style="list-style-type: none"> • Refer to the displayed message, and remeasure.
"ECG R-wave Not Detected" displayed after measurement	<p>R wave was not detected. Check the following points, and remeasure:</p> <ul style="list-style-type: none"> • First check the condition of the patient. • Make sure that electrodes are correctly applied. • Make sure the electrodes are not old or dry. • Make sure the patient's skin is not dirty.
Unstable "R-R interval [8]" displayed after measurement	<p>An unstable R wave interval was detected. Noise entered the signal because the patient moved.</p> <ul style="list-style-type: none"> • Have the patient rest quietly during measurement.
	<p>Noise entered the signal because of severe arrhythmia or patient convulsions. If there is severe arrhythmia, measurement accuracy may be poor. Judge the results after reading any error messages displayed after measurement.</p>
"*Weak Signal" displayed after measurement	<p>The amplitude of the detected signal was small, and only inaccurate data was obtained.</p> <ul style="list-style-type: none"> • Check the application positions of the sensors, and reposition them correctly.
"*Noise Interference" displayed after measurement	<p>Accurate data was not obtained, because there was noise in the signal.</p> <ul style="list-style-type: none"> • Eliminate the cause of the noise, and remeasure.
"*REJECT" displayed after measurement	<p>Wave data was deleted due to noise in the signal.</p> <ul style="list-style-type: none"> • Eliminate the cause of the noise, and remeasure.

About Maintenance

Principle of maintenance

Medical equipment, including VP-1000/2000 and TU-100[※], should be maintained so that the equipment functions are fully utilized while the safety of patients and operators is securely maintained.

As a principle, daily maintenance work such as checks before use should be performed by the operator.

However, in order to conduct a maintenance inspection at regular periods, about once every two years, and to secure the capabilities and safety of the equipment, it is necessary to designate a person in charge of maintenance work.

Management of consumables

Along with disposable consumables that are used daily, items applied to patients such as ECG leads are also considered consumables. It is recommended that spares be prepared beforehand, in view of possible cuts in the wire.

Daily consumables:

- SENSOR GEL PACK 101S
20 packs / Box (3 electrodes and 1 PCG pad / pack)
- Printing Paper
- Print Cartridges

P.No.047372



- Use only authorized accessories and options in order to avoid problems.
- Store the sensor gel below room temperature 10 to 35°C, avoiding high temperature and humidity, and direct light.

※ Pulse Wave Unit TU-100 is a optional unit for VP-1000.

Disposal

Follow local governing ordinances and recycling plans regarding disposal or recycling of batteries (Lead and Lithium) and other device components.

The composed main material for each part is as follows.

BP-203RPE II

Na me	Part	Material (s)
Package	Box Cushion Envelope	Corrugated Paper Paper Vinyl
Main Unit	Enclosure Internal Parts Chassis Battery on PCBoard	ABS General Electronic Parts Aluminium Lithium Battery
Api unit	Enclosure InternalParts Chassis	ABS General Electronic Parts Aluminum
CUFF No.20-23	Air bag and Hose	PVC, Nylon, PP (polypropylene) PE polyethelene)
ECG Electrode clip	Conductor Insulator Connector	Cupper PVC Brass
PCG Sensor	Enclosure Cushion Diaphragm Weight shielding	ABS Urethane PVC Brass Silicon
PPG Sensor RS-10 (as an option)	Bandage Top Insulator Connector	PVC Brass
PPG Sensor Extention SCP-10	Conductor Insulator Connector	Cupper PVC Brass

TU-100

Name	Part	Material (s)
Package	Box Cushion Envelope	Corrugated Paper Paper Vinyl
Main Unit	Enclosure Internal Parts	ABS General Electronic Parts
CAP Sensor (CAP-350)	Enclosure Shielding	ABS POM (polyester) Silicon
FAP Sensor (FAP-350)	Enclosure shielding	ABS POM (polyester) Silicon

Maintenance of the Device

WARNING



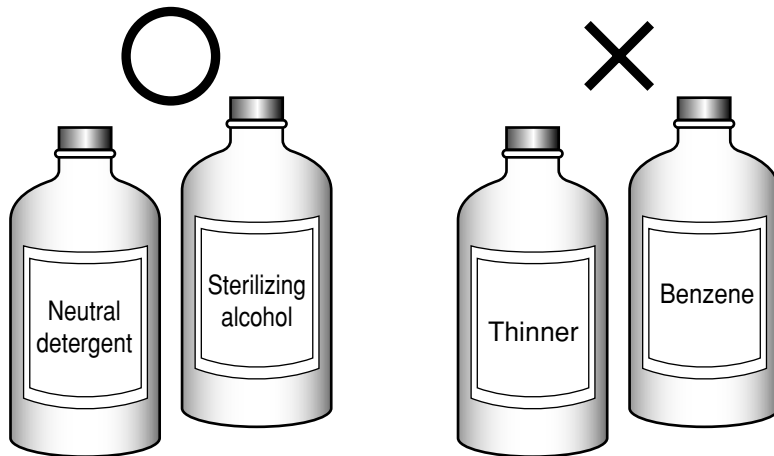
- The power plug should be pulled out from the electric outlet when conducting maintenance work as there is danger of electric shock.
- Keep the device and the accessories away from water, not to mention liquids getting inside the unit.
- When using sterilizing solutions, please follow the instructions of the manufacture.
- After cleaning the device, dry it completely before turning power on again.

Cleaning and sterilization

Based on the rules set by medical institutions, cleaning and sterilization should be conducted as below.

Surface cleaning

Use a damp cloth with a neutral detergent or sterilizing alcohol for cleaning the surface. However, do not wipe or wet connectors.



CAUTION

- Do not use solvents such as thinner and benzene for cleaning. Also avoid using cleaner with abrasives. This could damage unit surface.
- The main unit should not be sterilized with autoclave or gas (EOG, formaldehyde gas, high-density ozone, and the like).
- Ultraviolet radiation is harmful to liquid crystal display.

Cleaning of Sensors/Attachments



- Do not put solutions on the accessories. Do not wet the connectors.
- When using sterilizing solution, follow the manufacturer's instructions.



- Do not use solvents such as thinner and benzene for cleaning. Also avoid using cleaners with abrasives. This could damage the unit surface.
- Accessories should not be sterilized with autoclave or gases (EOG, formaldehyde gas, high-density ozone, and the like).

Cleaning and sterilization

Based on the rules set by medical institutions, cleaning and sterilization should be conducted as below.

Cuff and Cuff hose

Wipe with 30 - 50% isopropyl alcohol or 70% ethyl alcohol.

Never put any solutions inside the cuff or the cuff hose, lest certain adhesion should develop.

Care should be exercised to ensure that no fluid enters the cuff or the cuff hose at any time. The inside of cuff may adhere.

ECG sensor PCG sensor Tonometry sensor

Wipe with 30 - 50% isopropyl alcohol or 70% ethyl alcohol.

The wrist ECG clip electrodes and PCG sensor gel pad are disposable. They can be used, however, approx. 10 times of consecutive use. Please replace them as soon as following conditions are observed.

- Beginning of the day
 - Dry and not sticky
 - Dirty and not sticky
 - When used on the unhealthy skin, e.g. damp, trauma, infectious disease
-

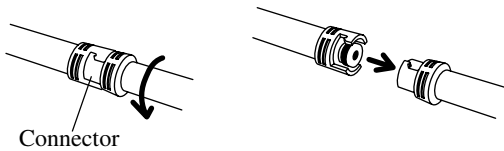
Cuff Replacement

Replace soiled or worn cuffs with new ones.

Note ! Make sure that all cuff connections are firmly secured. Air leaks will cause measurement errors.

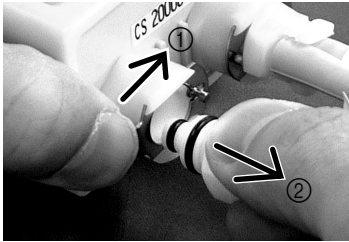
■ Arm Cuff Replacement

1. Rotate the connector in the direction of the arrow, then separate the air hose and connector.
2. Insert the connector for the new cuff into the air hose. Rotate in the direction of the arrow.



■ Replacing Ankle Cuffs

1. Pull out the connector ② while pressing the lever ① inward on the ankle cuff sensor box.
 - Since the lever is small and slippery, place your finger on its base while pressing.
2. Insert each connector for the new ankle cuff into the ankle cuff sensor box until it clicks.



Be careful not to mistake the right and left connectors when inserting them.

Technical Specification of BP-203RPEII

General:

Dimension

Main Unit:	297 (W) × 52 (H) × 250 (D) mm
API Unit:	297 (W) × 105 (H) × 205 (D) mm
ST-200A/100A: operation	380 (W) × 877 (H) × 565 (D) mm
ST-200A/100A: transportation	380 (W) × 743 (H) × 565 (D) mm

Weight

Main Unit:	approx. 3.0 Kg
API Unit:	approx. 3.6 Kg
ST-200A/100A	approx. 20.0 Kg

Display part

Method:	TFT color LCD
Display color:	256 color with back light
Resolution:	640 × 480 dots
Screen dimension:	170.9 mm (H) × 129.6 mm (V)

Safety Standards:

EN60601-1: 1990+A1: 1993+A2: 1995
Medical electrical equipment-Part1:
General requirements for safety
Class II

Protection Class:

Degree of Protection:

NIBP:	Type BF with defibrillator protection
ECG:	Type CF with defibrillator protection
PCG:	Type BF with defibrillator protection
PPG:	Type BF with defibrillator protection

Mode of Operation:

Other Standard:

Continuous
IEC60601-1-4: 1996 IEC 60601-1-4: 1996+A1: 1999
Medical electrical equipment Part1:
General requirement for Safety 4th
Programmable electrical medical Systems
BSEN1441: 1998 Medical devices-Risk analysis
ISO14971

Collateral Standard:

Environmental Conditions:

Power supply

Main Unit

Rating:	AC 120 V
Frequency:	50/60 Hz
Power consumption:	23 VA
	250 V, T1AH (time-lag,HBC)
	Cat.No.215001 (Little fuse,Inc.)

API Unit

Type 120

Rating:	AC 120 V
Frequency:	50/60 Hz
Power consumption:	45 VA
Fuse:	250 V, T2AH (time-lag,HBC)
	Cat.No.215002 (Little fuse,Inc.)

Operational temperature and humidity

Temperature range: 10 - 40 °C
Humidity range: 30 - 85 % (not condensed)
Atmospheric pressure: 700 - 1060 hPa

Storage and Transportation

Temperature range: -20 - 60 °C
Humidity range: 10 - 95 % (including condensed)
Atmospheric pressure: 500 - 1060 hPa

Dust and Water Resistance

Class IPX0
Reference: IEC 529 (1989); Degrees of protection provided by enclosures (IP Code)

EMC:

Reference Standard: EN60601-1-2(1993)+(Particular requirement) Medical electrical equipment Part1: General requirements for Safety .2.
Collateral Standard: Electromagnetic compatibility-Requirements and tests. EN55011 11 (1998)
Class B

Noninvasive blood pressure (NIBP):

Measurement method: oscillometric method
Measurement technology: Linear deflation
Pressure display range: 0,10 - 300 mmHg
NIBP Measurement range:

[Arm]

SYS 60 - 250 mmHg
MAP 40 - 235 mmHg
DIA 40 - 220 mmHg
Pulse rate 40 - 180 bpm

[Ankle]

SYS 40 - 250 mmHg

NIBP accuracy: Mean error and standard deviation per ANSI/AAMI SP-10

Pulse rate accuracy: ± 2 % or ± 2 beats

Usable cuff size: 10 - 15 cm(width of bladder)

Numbers of Cuff: 4 Right and Left Brachials, Right and Left of Ankles

Alarm Right Brachial SYS <70mmHg

Reference Standard: IEC60601-2-30(1999): Medical electrical equipment part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

EN1060-1(1995): Non-invasive sphygmomanometers.
General requirements.

EN1060-3(1997): Non-invasive sphygmomanometers-Part3: Supplementary requirements for electro-mechanical blood pressure measuring systems.

Technical Specifications of TU-100

PRODUCT NAME: Pulse Wave Unit

MODEL: TU-100

Pulse Wave Sensor Unit:

Measurement method:	Multi semiconductor strain gauge (2ch)
Frequency Characteristic:	DC - 300 Hz
Signal output range:	0 - 5.0 V
Sensitivity:	Variable (Automatic Gain Control)

Pulse Wave Velocity (PWV):

Pulse Wave Velocities are measured by the heart sound and dicrotic notch of each cuff pulse. R wave of ECG counts the heart rate and makes the noise elimination window for the heart sound

ECG:

Lead selection:	I
Display sensitivity:	Variable (Automatic Gain Control 2 ~ 30 mm/mV) 10mm/mV at Pacemaker:ON
Display sweep speed:	25 mm/s
Input impedance:	5 M ohm or more
CMRR:	100 dB or more
Frequency characteristics	
HPF:	0.52 Hz
LPF:	40 Hz (25Hz at Noise filter:ON)
Ham filter:	50 or 60 Hz (Automatic selecting filter)
Wave size selection:	Automatic selectivity control
R wave detection sensitivity:	200 μ V or less
Tall T wave rejection:	1.0 mV
HR display range:	0, 30 - 250bpm
HR measurements accuracy:	± 1 % or ± 1 beat
Electrode disconnect alarm:	Displayed
HR response time:	9 sec or less
HR averaging:	4 beats moving average at HR<120 8 beats moving average at 120 \leq HR
HR updating rate:	every beats
Pacemaker pulse rejection:	amplitude $\pm 2 \sim \pm 700$ mV pulse width 0.1 ~ 2.0 ms
Alarm	HR=0
Reference Standard:	EN60601-2-27 (1994): Medical electrical equipment-Part2: Particular requirements for the safety of Electro cardio graphic monitoring equipment. ANSI/AAMI EC13 Cardiac monitors,heart rate meters and alarms

Phonocardiograph (PCG):

Measurement method:	Electret Capacitance Microphone
Display sensitivity:	Variable (Automatic Gain Control)
Display sweep speed:	25 mm/s
Frequency characteristics:	
HPF:	43.1 Hz
LPF:	300 Hz
Wave size selection:	Variable Automatic selectivity control

Printer Output:

The parallel interface connector IEEE 1284-B signal compliant
14 pin (10214-55F3JL 3M)

Serial Port:

The serial interface connector MINI DIN 8pin (MD-S8100-10 HIROSE)



Medical Equipment

with respect to electric shock, fire and mechanical hazards only in accordance with UL60601-1 1st Edition and CAN/CSA C22.2 No. 601.1-M90

Standard Accessories:

RIGHT BRACHIAL CUFF No.20 (13 cm)	Not Available for order
LEFT BRACHIAL CUFF No.21 (13 cm)	Not Available for order
RIGHT ANKLE CUFF No.22 (13 cm)	Not Available for order
LEFT ANKLE CUFF No.23 (13 cm)	Not Available for order
RIGHT BRACHIAL CUFF HOSE No.4 (pink)	REF A037ZZ
LEFT BRACHIAL CUFF HOSE No.5 (blue)	REF A038ZZ
ANKLE CUFF HOSE UNIT	REF A039ZZ
PCG SENSOR	REF AS031Z
PCG WEIGHT	REF 049712
ECG ELECTRODE CLIP	REF AG0031
WRIST ECG ELECTRODE / PCG SENSOR GEL PAD (Bulk package 25 pieces each)	Not Available
OPERATION MANUAL	P.No.1730486

Optional Accessories:

BRACHIAL CUFF SET (10cm)	REF A057ZZ
BRACHIAL CUFF SET (13cm)	REF A048ZZ
BRACHIAL CUFF SET (15cm)	REF A055ZZ
ANKLE CUFF SET (10cm)	REF A056ZZ
ANKLE CUFF SET (13cm)	REF A049ZZ
ANKLE CUFF SET (15cm)	REF A053ZZ
SENSOR GEL PACK 101S (20packs/box) :Set of WRIST ECG ELECTRODE AND PCG SENSOR GEL PAD	REF 047372
SERVICE MANUAL	REF AN032Z
PRINTER	
TROLLY ST-100A/200A	

Limited Warranty

Omron Healthcare, Inc. warrants the Cardio Vascular Profiling System (VP-1000/2000), including the MAIN Unit , API Unit and TU-100, to be free from defects in materials and workmanship under normal use and with appropriate maintenance for a period of 3 years from the date of purchase. Accessories included in the original system purchase, including blood pressure cuffs, air tubes, connection cables, power cords and memory cards are warranted to be free from defects in materials and workmanship for a period of 1 year from the date of purchase. Consumables, including printer paper, are warranted only that such parts will be free from defects in materials and workmanship at the time of purchase.

Omron will repair or replace (at our option) within a reasonable period of time any item returned to us within the warranty period. The following information is required:

- Customer Service case number (call Omron Healthcare Professional Services to obtain)
- Letter stating the problem
- Serial number
- Copy of invoice or other proof of Purchaser's name, date of purchase, phone number and address

To return the product to Omron, call Omron Healthcare Professional Services.

There will be no charge for parts and labor performed by Omron to correct warranted defects and Omron will pay the cost of shipping the repaired unit back to you. Equipment that has been damaged or is excluded from this warranty will be repaired for a fee.

Equipment or any part thereof that is repaired during the limited warranty period will be warranted under the terms of the limited warranty for a period not to exceed the remaining term of the original limited warranty or six (6) months, whichever is longer.

Transportation damage: Omron will not be responsible for damage in transit to Omron. Contact your freight company to submit claims for shipping damage. In the case of damage in transit from Omron, Omron will submit a claim to the shipping company. Keep all packaging materials for review by the shipping company and as proof of mishandling. Do not operate the equipment after discovering transit damage as this may negate the ability to process the claim with the carrier.

Exclusions and Limitations:

1. This warranty applies to the original purchaser only and is not transferable.
2. This warranty does not cover misuse of the equipment. Misuse includes but is not limited to:
 - Misuse as described in the Instruction Manual
 - Use of faulty or abnormal electrical power
 - Affixing the equipment to any nonstandard accessory attachment
 - Having the equipment modified, improperly disassembled, serviced or reassembled by anyone other than Omron unless authorized in writing by Omron Healthcare, Inc.
 - Installation in a manner that does not conform to local building, electrical and fire codes or, in their absence, the recommendation in the Instruction Manual.
3. This warranty does not cover equipment that has failed due to neglect, accident, Acts of God such as fire, earthquake, flood, lightning, other acts of nature, environmental disruption, or a cause other than the equipment.
4. This warranty does not cover any equipment on which the serial number plate has been removed, modified, or made illegible.
5. Omron will not be responsible for the effect on safety, reliability or performance of the warranted equipment if:
 - Assembly operations, extensions, adjustments, modifications or repairs are performed by persons other than Omron or persons authorized by Omron to perform such services on Omron's behalf,
 - Electrical installation does not comply with applicable national and international standards, including the requirements of the international electrotechnical commission, or
 - The warranted product is not used in accordance with the Instruction Manual.
6. Omron will have no obligation to enhance or upgrade any unit once manufactured.
7. Omron will not guarantee availability of repair and maintenance parts longer than eight (8) years after discontinuation of the equipment.
8. Omron reserves the right to withhold approval of a warranty claim pending visual inspection of the alleged defect.

Omron's sole responsibility shall be to repair or replace the product within the terms stated alone. OMRON SHALL NOT BE LIABLE FOR ANY LOSS OR DAMAGE OF ANY KIND, INCLUDING INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING DIRECTLY OR INDIRECTLY, FROM ANY BREACH OF ANY WARRANTY, EXPRESS OR IMPLIED, OR ANY OTHER FAILURE OF THIS PRODUCT. ALL IMPLIED WARRANTIES, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS, ARE LIMITED TO THE DURATION OF THIS WRITTEN WARRANTY. THIS WARRANTY SUPERCEDES ALL OTHER ORAL OR WRITTEN WARRANTIES.

OMRON Cardio Vascular Profiling System

Call this number for warranty service and repair.

Omron Healthcare Customer Service and Technical Support.

1-800-829-6427

Local : 210-690-6200

Toll Free

5850 Fusion Drive
San Antonio, Tx 78249

Business Hours
8:30-4:30 PM "Central Time"
Mon - Fri
We reserve the right to close or
change business hours, without
notice.

Visit our website at www.omronhealthcare.com

Memo

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